



## Ciprofloxacin (Ciloxan®) drops for infection

PLEASE READ BEFORE USING THE DROPS. KEEP IT SOMEWHERE SAFE SO YOU CAN READ IT AGAIN.

### Name of drug

**Ciprofloxacin drops** (sip-roh-flox-ass-in)

**Common brand:** Ciloxan®

### Why has my child been prescribed ciprofloxacin drops?

- Middle ear infections are common, painful infections in children. Germs multiply in the middle ear causing a build-up of pressure that stretches the ear drum. In around 1 in 7 children, the ear drum bursts, releasing a liquid (medical term: 'discharge') that can be seen coming out of the ear.
- While the hole in the ear drum is open it is important to start giving the ear drops as soon as possible on Day 1 (day of study entry) and then regularly (as your GP/nurse has explained) **each day for 7 days**.
- This will make sure that the antibiotic has a chance to kill the bacteria causing the infection.
- Most symptoms of ear infections improve or stop within **4 to 7 days** and the ear drops may help to shorten the time taken for your child's ear discharge to get better.
- Ciprofloxacin drops are often used to treat eye infections, but are safe to be used in the ears as well.

### How much and when to give the ciprofloxacin drops

- We would like you to give 4 drops x 3 times daily for 7 days:
  - > in the morning;
  - > in the early afternoon, e.g. straight after school;
  - > in the evening.
- Try to space these times out as evenly as possible.
- Give the drops at about the same time each day.
- The dose will be shown on the medicine label.
- **It is important that you follow the instructions on the medicine label about how much to give.**

### How to give the drops

- Wash your hands thoroughly with soap and hot water.
- Shake the bottle.
- Wipe away any discharge that can easily be removed with a tissue before giving the drops.
- Your child needs to have their head tilted to one side (they could rest their head on a pillow) with the affected ear facing up. It may be easier to have your child lying down on their side if that is more comfortable.
- Put the tip of the dropper just inside the ear hole. Try to avoid touching the nozzle on to the ear. Gently squeeze the drop(s) into the ear.
- **Hint:** If you are finding it difficult to put the drops into the ear canal, it might help to gently pull the ear to open up

*the ear canal.*

- Gently, but firmly and quickly, press on the flap of skin in front of the ear canal several times to help the drops go down the ear hole.
- Keep your child in the same position for a few minutes. This will help the drops to reach the ear drum.
- Wipe the nozzle with a clean tissue after each use.
- Do not put cotton wool (or anything else) into the ears during the 7 days of treatment.

### When will the ear drops start working?

- The drops will start to work straight away but it may take 2–3 days before your child starts to feel better.
- It is important that you give the whole course of drops that your doctor has prescribed, even when your child feels better. This is to make sure that all the bacteria are killed and the infection doesn't come back.

### What if my child is sick (vomits) after I give her/him the drops?

- You do not need to worry if your child is sick, as the drops will still work.
- If your child continues to vomit and you are concerned, please contact your GP or NHS 111 telephone service, for advice

### What if I forget to give it?

- Do not give the missed dose. Just give the next dose as usual.

### What if I give too much?

- It is unlikely that you will cause any harm if you give your child extra drops by mistake. Much higher doses are routinely given by mouth.
- If you are worried that you may have given your child too much, contact your doctor or local NHS 111 telephone service. Have the medicine or packaging with you if you telephone for advice.

### Are there any possible side-effects?

We use medicines to make our children better, but sometimes they have other effects that we don't want (side-effects).

#### Very rare side-effects you must do something about

If your child is short of breath or is wheezing, or their face, lips or tongue start to swell, or they develop a rash, they may be allergic to ciprofloxacin. **STOP** using the drops. Take your child to hospital or call an ambulance **straight away**.



### Important things to know about taking antibiotics

- Try to give the medicine at about the same times each day, to help you remember, and to make sure that there is the right amount of medicine in your child's body to kill the bacteria.
- Only give this medicine to your child for their current infection that you have agreed to take part in the study for, and for **7 days only**.
- **Never save** medicine for future illnesses.



- Only give the antibiotic to the child for whom it was prescribed. Never give it to anyone else, even if their condition appears to be the same, as this could do harm.
- Antibiotics only kill bacteria; they do not kill viruses. This means that they do not work against colds, sore throats, flu or other infections that are caused by viruses. Your doctor will not prescribe antibiotics for these illnesses.

### Other side-effects you need to know about

- Your child may develop a rash or itching in the ear(s) while using the drops. This will stop when the course of treatment is finished. If it is a problem, contact your doctor for advice.
- There may, sometimes, be other side-effects that are not listed above. If you notice anything unusual and are concerned, contact your doctor **and** the REST study team [redacted].

### Remember

- Keep the drops in a cupboard, away from children, heat and direct sunlight - **do not** keep in the fridge.
- Keep the drops in the container they come in.
- Try to keep your child's ears dry during the time they are having the drops, especially at bathtime.
- If you have any questions about how to use the medicine, contact the REST study team on [redacted] or email [redacted].
- The study is not intended to replace your child's usual medical care. If you have concerns about your child's illness, please contact your GP or NHS 111 in the usual way.

### Can other medicines be given at the same time as ciprofloxacin drops?

- You can give your child medicines that contain paracetamol or ibuprofen to help treat any pain or high temperature, unless your doctor has told you not to. Always follow the dosing instructions on the packaging or from your doctor.
- Check with your doctor or pharmacist **before** giving any other medicines to your child, including herbal or complementary medicines. However, most medicines can be given safely while using ciprofloxacin drops.

### What to do if your child's symptoms get worse

- Contact your doctor or local NHS 111 telephone service if your child does not appear to be getting better after a few days or if they have any of the following symptoms:-
  - > increasing pain
  - > high temperatures
  - > headaches
  - > irritability
  - > or reduced feeding (particularly if your child is under 2 years old).
- These drops are intended for use in the ear for which the doctor or nurse prescribed them at your REST study appointment. If your child's other ear starts to hurt or you see discharge do not use the ear drops in this ear. Contact your GP surgery and also the Trial Research Nurse [redacted] or email [redacted].



# the runny ear study



## “Just In Case” or “Delayed” Antibiotic Prescriptions

PLEASE READ BEFORE USING MEDICINES. KEEP IT SOMEWHERE SAFE SO YOU CAN READ IT AGAIN.

### Why has my child been given a “just in case” or “delayed” prescription for antibiotics?

- Middle ear infections are common, painful infections in children. Germs multiply in the middle ear causing a build-up of pressure that stretches the ear drum. In around 1 in 7 children, the ear drum bursts, releasing a liquid (medical term: ‘discharge’) that can be seen coming out of the ear.
- Most people believe that the ear pain improves when the ear drum bursts, but research shows the pain is the same, with or without the ear drum bursting.
- Most symptoms of ear infections improve or stop within **4 to 7 days**.
- Not every child needs antibiotics but nearly all children in the UK with ear infections and discharge are given antibiotics immediately - these can cause side-effects like:-
  - > rashes
  - > diarrhoea and vomiting
  - > and, very rarely, severe allergic reactions
 They can also make the germs in a child’s body resistant to antibiotics.
- We want to see if a “delayed” antibiotic prescription (a prescription which is not “cashed” unless the infection does not get better on its own or the symptoms get worse) could be an alternative treatment for ear discharge – studies in other infections suggest this can be just as effective and safe, but with fewer side-effects.

### When to give the antibiotics

- Your doctor/nurse will have given you a prescription for amoxicillin (or clarithromycin or other antibiotic, if your child is allergic to amoxicillin) and will have advised you to “**wait and see**” over the **next 3 days**, before “cashing” it in.
- If your child’s ear infection improves, it is unlikely that you will have to give them the antibiotics.
- If at **any time** during the **first 3 days** your child’s condition worsens, start giving the antibiotics and if you are concerned, contact your GP. See the section “What to do if your child’s symptoms get worse” on the next page for signs to look out for in the first 3-4 days.

### How much to give


- The amount to give depends on which antibiotic your child has been prescribed and how old they are – your doctor/nurse will have worked out the correct dose for your child.
- If your child has been given a prescription for **amoxicillin (liquid or tablets)** you should give it **3 times daily for 7 days**:

- > in the morning;
- > in the early afternoon, e.g. straight after school;
- > in the evening.

- If your child has been given a prescription for **clarithromycin (liquid or tablets)** you should give it **2 times daily for 7 days**:

- > in the morning;
- > in the evening.

- Try to space these times out as evenly as possible.
- Give the antibiotic at about the same time each day.
- The dose will be shown on the medicine label.

 **It is important that you follow the instructions on the medicine label about how much to give.**

### When will the antibiotic start working if I have to “cash in” the prescription?

- The antibiotic will start to work straight away but it may take another **2–3 days** before your child starts to feel better.
- It is important that you give the whole course of antibiotics that your doctor has prescribed, even when your child feels better. This is to make sure that all the bacteria are killed and the infection doesn’t come back.

### What if I forget to give it?

- Do not give the missed dose. Just give the next dose as usual.

### What if I give too much?

- Higher doses are used for serious infection. If you are still worried that you may have given your child too much, contact your doctor or local NHS 111 telephone service as soon as possible. Have the medicine or packaging with you if you telephone for advice.

### Are there any possible side-effects?

We use medicines to make our children better, but sometimes they have other effects that we don’t want (side-effects).

#### Very rare side-effects you must do something about

- If your child is short of breath or is wheezing, or their face, lips or tongue start to swell, or they develop a rash, they may be allergic to the antibiotic.



**STOP** using the medicine. Take your child to hospital or call an ambulance **straight away**.

#### Other side-effects you need to know about

- The most common side-effects for **amoxicillin** are:
  - > skin rash
  - > nausea
  - > diarrhoea



### Important things to know about taking antibiotics

- Try to give the medicine at about the same times each day, to help you remember, and to make sure that there is the right amount of medicine in your child's body to kill the bacteria.
- Only give this medicine to your child for their current infection that you have agreed to take part in the study for, and for **7 days only**.
- **Never save** medicine for future illnesses.



- Only give the antibiotic to the child for whom it was prescribed. Never give it to anyone else, even if their condition appears to be the same, as this could do harm.
- Antibiotics only kill bacteria; they do not kill viruses. This means that they do not work against colds, sore throats, flu or other infections that are caused by viruses. Your doctor will not prescribe antibiotics for these illnesses.

- The most common side-effects for **clarithromycin** are:
  - > abdominal pain
  - > diarrhoea
  - > nausea
  - > vomiting
  - > change in sense of taste
- If your child develops any of the above side-effects contact your doctor for advice.
- There may, sometimes, be other side-effects that are not listed above. If you notice anything unusual and are concerned, contact your doctor **and** the REST study team [redacted].

### Remember

- Keep the antibiotic in the container it comes in and out of the reach of children.
- If you have any questions about how to use the medicine, contact the REST study team on [redacted] email [redacted].
- The study is not intended to replace your child's usual medical care. If you have concerns about your child's illness, please contact your GP or NHS 111 in the usual way.

### Can other medicines be given at the same time as antibiotics?

- You can give your child medicines that contain paracetamol or ibuprofen to help treat any pain or high temperature, unless your doctor has told you not to. Always follow the dosing instructions on the packaging or from your doctor.
- Check with your doctor or pharmacist **before** giving any other medicines to your child, including herbal or complementary medicines. However, most medicines can be given safely while using antibiotics.

### What to do if your child's symptoms get worse

- Contact your doctor or local NHS 111 telephone service if your child does not appear to be getting better after a few days or if they have any of the following symptoms:-
  - > increasing pain
  - > high temperatures
  - > headaches
  - > irritability
  - > or reduced feeding (particularly if your child is under 2 years old).
- If your child's other ear starts to hurt or you see discharge contact your GP surgery **and** also the Trial Research Nurse [redacted] or email [redacted].



# the runny ear study





# Immediate Antibiotic Prescriptions

PLEASE READ BEFORE USING MEDICINES. KEEP IT SOMEWHERE SAFE SO YOU CAN READ IT AGAIN.

## Why has my child been given a prescription for antibiotics?

- Middle ear infections are common, painful infections in children. Germs multiply in the middle ear causing a build-up of pressure that stretches the ear drum. In around 1 in 7 children, the ear drum bursts, releasing a liquid (medical term: 'discharge') that can be seen coming out of the ear.
- Most people believe that the ear pain improves when the ear drum bursts, but research shows the pain is the same, with or without the ear drum bursting.
- Most symptoms of ear infections improve or stop within **4 to 7 days**.
- It is current standard treatment that all children in the UK with ear infections and discharge are given antibiotics immediately.

## When to give the antibiotics

- Your doctor/nurse will have given you a prescription for amoxicillin (or clarithromycin or other antibiotic, if your child is allergic to amoxicillin) and advised you to **start giving the antibiotic straightaway**.

## How much to give

- The amount to give depends on which antibiotic your child has been prescribed and how old they are – your doctor/nurse will have worked out the correct dose for your child.
- If your child has been given a prescription for **amoxicillin (liquid or tablets)** you should give it **3 times daily for 7 days**:
  - > in the morning;
  - > in the early afternoon, e.g. straight after school;
  - > in the evening.
- If your child has been given a prescription for **clarithromycin (liquid or tablets)** you should give it **2 times daily for 7 days**:
  - > in the morning;
  - > in the evening.
- Try to space these times out as evenly as possible.
- Give the antibiotic at about the same time each day.



The dose will be shown on the medicine label.

**It is important that you follow the instructions on the medicine label about how much to give.**

## When will the antibiotic start working?

- The antibiotic will start to work straight away but it may take **2–3 days** before your child starts to feel better.
- It is important that you give the whole course of

antibiotics that your doctor has prescribed, even when your child feels better. This is to make sure that all the bacteria are killed and the infection doesn't come back.

## What if I forget to give it?

- Do not give the missed dose. Just give the next dose as usual.

## What if I give too much?

- Higher doses are used for serious infection. If you are still worried that you may have given your child too much, contact your doctor or local NHS 111 telephone service as soon as possible. Have the medicine or packaging with you if you telephone for advice.

## Are there any possible side-effects?

We use medicines to make our children better, but sometimes they have other effects that we don't want (side-effects).

### Very rare side-effects you must do something about

- If your child is short of breath or is wheezing, or their face, lips or tongue start to swell, or they develop a rash, they may be allergic to the antibiotic.
- **STOP** using the medicine. Take your child to hospital or call an ambulance **straight away**.

### Other side-effects you need to know about

- The most common side-effects for **amoxicillin** are:
  - > skin rash
  - > nausea
  - > diarrhoea
- The most common side-effects for **clarithromycin** are:
  - > abdominal pain
  - > diarrhoea
  - > nausea
  - > vomiting
  - > change in sense of taste
- If your child develops any of the above side-effects contact your doctor for advice.
- There may, sometimes, be other side-effects that are not listed above. If you notice anything unusual and are concerned, contact your doctor **and** the REST study team [redacted].

## Remember

- Keep the antibiotic in the container it comes in and out of the reach of children.
- If you have any questions about how to use the medicine, contact the REST study team on [redacted] or email [redacted]

### Important things to know about taking antibiotics

- Try to give the medicine at about the same times each day, to help you remember, and to make sure that there is the right amount of medicine in your child's body to kill the bacteria.
- Only give this medicine to your child for their current infection that you have agreed to take part in the study for, and for **7 days only**.
- **Never save** medicine for future illnesses.

- Only give the antibiotic to the child for whom it was prescribed. Never give it to anyone else, even if their condition appears to be the same, as this could do harm.
- Antibiotics only kill bacteria; they do not kill viruses. This means that they do not work against colds, sore throats, flu or other infections that are caused by viruses. Your doctor will not prescribe antibiotics for these illnesses.



- The study is not intended to replace your child's usual medical care. If you have concerns about your child's illness, please contact your GP or NHS 111 in the usual way.

### Can other medicines be given at the same time as antibiotics?

- You can give your child medicines that contain paracetamol or ibuprofen to help treat any pain or high temperature, unless your doctor has told you not to. Always follow the dosing instructions on the packaging or from your doctor.
- Check with your doctor or pharmacist **before** giving any other medicines to your child, including herbal or complementary medicines. However, most medicines can be given safely while using antibiotics.

### What to do if your child's symptoms get worse

- Contact your doctor or local NHS 111 telephone service if your child does not appear to be getting better after a few days or if they have any of the following symptoms:-
  - > increasing pain
  - > high temperatures
  - > headaches
  - > irritability
  - > or reduced feeding (particularly if your child is under 2 years old).
- If your child's other ear starts to hurt or you see discharge contact your GP surgery and also the Trial Research Nurse [redacted] or email [redacted]).



# the runny ear study

# REST: Participant Withdrawal Information Sheet



Fax number: [REDACTED]

or

Encrypted email: [REDACTED]

## **REST: Immediate oral, immediate topical or delayed oral antibiotics for acute otitis media with discharge (AOMd)**

### **Participant study withdrawal Information Sheet**

#### **1. Overview**

All patients and legal guardians in the REST study have the right to withdraw at any time without giving a reason in accordance with Good Clinical Practice, and the Helsinki Declaration. This information sheet details the reporting of participant withdrawal.

#### **2. Responsibilities of the Study Team**

The Study team will provide each practice with this SOP and a set of Participant Withdrawal Forms (appended to this SOP).

#### **3. Responsibilities of the Researcher**

The nominated Lead GP/PI within each practice will be responsible for completion of a Participant Withdrawal Form, should a participant wish to withdraw from the study. The Lead GP/PI will be required to send a copy of the withdrawal form to the Study team (either by secure email or secure fax) and to file the original in the participant's medical records with the completed consent form.

All Participant Withdrawal Forms must be signed by the Lead GP/PI.

#### **4. Reasons for Withdrawal, Use of Data & Patient Follow-Up**

Participants are free to withdraw from the study at any time without giving a reason and without any impact on usual care. However, if you are aware of the reason for withdrawal, this should be specified on the Participant Withdrawal Form.

*N.B.* If patient and/or legal guardian have previously expressed a wish to withdraw from the study, you should not contact them for the purpose of collecting this information. Please complete the form to the best of your knowledge only.

Four options are provided which relate to the nature of the withdrawal. The member of staff withdrawing the patient should select one option only from the following as applicable:

*Withdrawal of consent for follow up:*

- [a] Participant wishes to withdraw from the study but consent to use of data already provided for the purposes of analysis; participant does not wish to be followed up.
- [b] Participant wishes to withdraw from the study and withdraw permission for any baseline and routinely collected data to be analysed as part of the study; participant does not wish to follow up.

*Partial withdrawal of consent for follow up:*

- [c] Participant does not wish to complete further routine data collection (Inc. stool sample collection) or follow up questionnaires but participant is willing for research team to access medical notes to conduct 3 months' case notes review.



## REST: Participant Withdrawal Information Sheet



Fax number: [REDACTED]

or

Encrypted email: [REDACTED]

- [d] Participant does not wish to complete further routine data collection or follow up questionnaires, but participant is willing to collect a stool sample at 14 days and 3 months.

*Where the Participant has expressed a wish to withdraw from any further follow up, assume that previously provided consent to use of data already provided is still valid (i.e. option b) unless otherwise stated.*

Fax number: [REDACTED]

or

Encrypted email: [REDACTED]

# the runny ear study

## CHILD INFORMATION SHEET (6-10 YEARS)

**We want to find out the best way to help children with runny ears  
Do you want to join our study?**

### **What is this study about?**

To see if ear drops can make children's runny ears better.

### **Why me?**

We are asking children with runny ears who are up to 16 years old to take part.

### **Why is it a good idea to take part?**

You can help find out what is the best way to make runny ears better.

### **Do I have to do this?**

No, it's up to you. You can say no at any time and you don't have to say why.

### **What will happen?**

- 1) You will write your name on a form to say you want to take part.
- 2) When you go in to see the doctor or nurse, your mum or dad will answer some questions about you and your illness.
- 3) The doctor or nurse may give you some ear drops or some medicine to swallow, to try at home. Only some children will get ear drops. We want to find out whether ear drops, medicine you take if your runny ear doesn't get better or medicine you take straightaway, is best for children with runny ears.
- 4) Your mum or dad will give you the ear drops or the medicine for 7 days, and write down how you are in a special book for the next week.

### **What happens to your special book?**

Your book will be kept in a safe place at the University of Bristol. We will look at your book and the books filled in by other mums and dads, think about how long it took for you to feel better and decide on the best way for doctors to treat other children like you who have runny ears. We will write about what we find but we will not tell anyone your name.

### **What if I change my mind?**

You can change your mind at any time and nobody will be upset. Tell your mum or dad you do not want to do it anymore and they will tell the researcher. The researcher will then take your name out of the study.



IRAS ID: 229293



The Runny Ear Study is funded by the National Institute for Health Research's HTA Programme HTA 16/85/01



# the runny ear study

## CHILD INFORMATION SHEET (11-16 YEARS)

**We want to find out the best way to help children with runny ears  
Do you want to join our study?**

### **What is this study about?**

To see if antibiotic ear drops can make children's runny ears better more quickly, instead of taking antibiotic medicines that are tablets or liquid. Many children in the UK are given antibiotic medicines by mouth as soon as they get runny ears; but it may be possible to use antibiotic ear drops instead and this is what we are looking at in this study.

### **Why me?**

We are asking children with runny ears who are up to 16 years old to take part.

### **Why is it a good idea to take part?**

You can help find out what is the best way to make runny ears better more quickly.

### **Do I have to do this?**

No, it's up to you. You can say no at any time and you don't have to say why.

### **What will happen?**

- 1) When you go in to see the doctor or nurse, you and your mum or dad will answer some questions about your illness.
- 2) You will answer some short questions and write your name on a form to say you want to take part.
- 3) The doctor or nurse will give you a prescription for the antibiotic ear drops or for an antibiotic medicine (liquid or tablets depending on how old you are), to take at home. Only some children will get ear drops. We want to find out what is best for children with runny ears - ear drops given immediately, medicine you take a few days later if your runny ear doesn't get better or medicine you take straightaway.
- 4) Your mum or dad will help to give you the ear drops or the medicine until you feel better, and write down how you are in a diary, called "Your Child's Symptom and Recovery Questionnaire", for the next two weeks.

### **What happens to your symptom diary?**

Your diary will be kept in a safe place at the University of Bristol. We will look at your diary and the diaries filled in by other families taking part in the study, think about how long it took for you to feel better and decide on the best way for doctors to treat other children like you who have runny ears. We will write about what we find but we will not tell anyone your name.

## What if I change my mind?

You can change your mind at any time and nobody will be upset. Tell your mum or dad you do not want to do it anymore and they will tell the researcher. The researcher will then take your name out of the study.



IRAS ID: 229293



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Participant ID:

The Runny Ear Study is funded by the National Institute for Health Research's HTA Programme HTA 16/85/01

## CONSENT TO TAKE PART IN THE RUNNY EAR STUDY

**I understand and agree: (Points 1-7 must be initialled by the parent for the child to be included in the study)**

INITIAL  
boxes

1. I have read the Parent Information Sheet (v2.0, date: 10/05/2018) for the Runny Ear Study and have had any questions answered satisfactorily.
2. My child's participation is voluntary and he/she can stop taking part at any time without giving any reason and without his/her medical care or legal rights being affected.
3. My child will be given one of 3 treatments - antibiotic ear drops, "just in case" or "delayed" oral antibiotics or immediate oral antibiotics; I am willing to give the allocated medicine to my child as advised by my child's doctor/nurse.
4. I am willing to complete my child's symptom and recovery questionnaire (online or on paper ) for 14 days and receive regular telephone calls from the study Research Nurse.
5. I am willing to complete a questionnaire 3 months after study entry (online or on paper) about my child's health.
6. That my child's medical records and data collected during the study, may be looked at by NHS-authorized researchers, from regulatory authorities or from the NHS Trust, as relevant to this research. I give permission for these persons to access my child's records.
7. That my child can take part in the above study.

**The following points (8-12) are optional:**

8. I am willing to collect a stool sample from my child on day 14 and 3 months after study entry.
9. I am willing for my child's stool sample to be retained for future research in microbial infections.
10. I am willing to be invited to take part in a telephone interview about my views on the treatment of children's ear infections with no commitment to take part.
11. That the information collected about my child may be used to support other research in the future, and may be shared anonymously with other researchers.
12. **(For children recruited at OOH and WIC sites only)** That our GP can be informed that myself and my child are taking part in this study.

**Child's Name (please print):**

[illegible]

**Parent's Name (please print):**

[illegible]

**Parent's signature:**

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Date:

D	D	/	M	M	/	Y	Y	Y	Y
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**Consenting Clinician's Name (please print):**

[illegible]

**Clinician's signature:**

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Date:

D	D	/	M	M	/	Y	Y	Y	Y
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**Paperwork management instructions:** Complete one copy.

- **Send to Bristol Trial Centre via secure fax [REDACTED] or encrypted email [REDACTED] TODAY.**
- Photocopy and give copy to parent (put it in the shopping bag provided in the Participant Pack).
- Scan into child's medical record and store in the REST Site File (these will be collected at the end of the study).

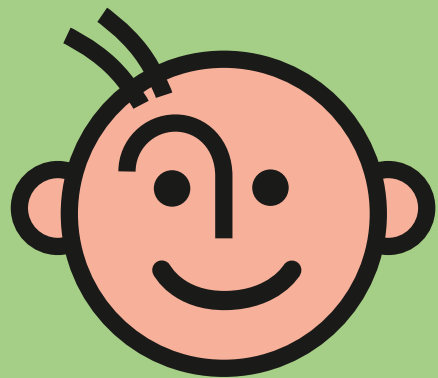


# the runny ear study

Immediate Oral, Immediate Topical or Delayed Oral Antibiotics  
for Acute Otitis Media with Discharge: REST

PARENT  
INFORMATION  
SHEET





Participation in the Study is completely voluntary  
and if you do decide not to take part,  
this will not affect or change the treatment and care  
your child receives from the doctor or nurse.

The Study is for research purposes  
and your consent is needed before  
you and your child can take part.



## WHAT IS THE PURPOSE OF THE STUDY?

Middle ear infections are common painful infections in children. Germs multiply in the middle ear causing a buildup of pressure that stretches the ear drum. In around 1 in 7 children, the ear drum bursts, releasing a liquid.

This study is looking at the best way to treat children with a middle ear infection, medically known as acute otitis media (AOM). At the moment nearly all UK children with AOM and discharge (AOMd) seen by their GP or nurse are treated with antibiotics by mouth. However, taking antibiotics by mouth can cause side-effects like rashes, diarrhoea and vomiting and more rarely, severe allergic reactions. They can also make the germs in a child's body resistant to antibiotics.

However, it may be possible to use alternative treatments for ear discharge:

- Using antibiotic eardrops: research has already shown that these are better than antibiotics by mouth for children with runny ears and grommets, probably because the antibiotics are given directly to the place they are most needed. The drops can be used for AOMd with a burst ear drum in the same way.
- Using a “just in case” or ‘delayed’ antibiotic prescription (where parents are advised to wait to see if the child's infection improves without antibiotics): our studies in other infections suggest this can be just as effective and safe, but with fewer side-effects.

The GP or nurse will randomly allocate your child to one of three treatments to treat AOMd. The treatment your child will receive is down to chance, like tossing a coin.

In this study we would like to find out whether giving an antibiotic ear drop or a delayed antibiotic by mouth is as good as immediately giving antibiotics by mouth for children with AOMd. AOMd is a common and painful infection for children so it is important that any new treatment works at least as well as the standard, immediate antibiotic treatment.

### WHY HAVE MY CHILD AND I BEEN INVITED TO TAKE PART?

We are looking for 400 children age 12 months to 16 years to take part in this study. Your GP or nurse will have invited you and your child to take part in this study because your child has AOMd. Taking part in this study will not affect the usual care your child receives from their GP for any other conditions.

### WHAT ARE THE ANTIBIOTIC EAR DROPS AND ARE THEY SAFE?

We are using ciprofloxacin eye drops (Ciloxan 0.3%) as the study antibiotic ear drops. Ciprofloxacin is widely available in the UK and is safe to be used in the ears as well as eyes. Ciprofloxacin is the most commonly used treatment for external ear infections.

Ear drops are as safe as other medicines commonly used to treat ear infections in children, such as antibiotics by mouth.

We do not expect any children taking part in this trial to have any serious side-effects if they are allocated to receive the drops. A rash or itching of the skin in the outer ear may occur, but this will stop when the treatment is finished.



In rare cases your child may be allergic to ciprofloxacin.  
If your child is short of breath or is wheezing, or their face, lips or tongue start to swell, or they develop a rash, they need immediate medical treatment.

### WHAT HAPPENS IF MY CHILD AND I TAKE PART?

- You will be asked some questions about your child's illness and general health.
- The doctor or nurse will look in your child's ears and check if it's safe for them to take part in the study.
- You will be asked to sign a consent form for you and your child to take part in the study (if your child aged 6 -16 years can understand the study and what is involved for them they may sign their own consent form).
- Your child will be randomly allocated to one of the three treatment groups; immediate oral antibiotics, delayed oral antibiotics or ear drops.
- If your child is allocated to the ear drops group, you will be shown how to give them to your child until their ear discharge is better.
- You will be asked to complete a questionnaire (online or on paper) about your child's symptoms, ear discharge and any antibiotic or oral painkilling medicines, to be filled in today and for the next 13 days (14 days in total).

- The study team will phone you as soon as they get your details and up to a maximum of 4 more times over the next 13 days to answer any questions and collect information from the paper questionnaire. If you've chosen to complete the questionnaire online, we will call you to check if there are any problems and answer any questions you may have.
- If you consent to collect your child's stool sample, the study team will post you a sample collection kit and ask you to collect a stool sample on day 14 of the study. The study team will pre-label the stool sample swab with your child's study ID - you will be asked to write the date on the sample tube when it is taken. It is very important you write the exact date that you take the sample. The research nurse will remind you about the stool sample during the follow up calls. At 3 months, another stool sample kit will be sent to you to collect another sample.
- After 3 months, you will either be sent a link to an online questionnaire or sent a paper copy of the questionnaire (with a pre-paid return envelope), for you to complete. The questionnaire is about your child's general health.
- With your permission NHS-approved researchers will look at your child's medical records after 3 months, to collect information on any other ear discharge episodes your child may have had (you do not need to be present).
- In appreciation of you and your child's time in taking part in the study, we will send you High Street shopping vouchers at the end of the study. Children aged 10-16 will receive a £10 voucher for taking part and those under 10 years will receive a piggy bank.

- You might be invited to be interviewed about your trial experiences at a later date (only some parents will be invited) and participation is optional.
- Most children with runny ears recover within one week but up to 30% can still be expected to have some pain, and up to 20% to still have some discharge. We suggest you contact your GP if your child's symptoms are not improving by day 7, or sooner if they are getting worse or you have any concerns.

### WHAT HAPPENS IF I TAKE PART IN AN INTERVIEW?

- A researcher **might** phone to invite you to be interviewed for around 30 minutes (but no more than 45 minutes). They will answer your questions and if you agree, arrange a convenient time for the telephone interview.
- If you are interviewed, you will be asked about your views and experiences of the way your child's ear pain was treated by the doctor and how you think children's ear pain should be treated in the future. With your permission, the researcher **might** audio-record the interview.
- All the interviews conducted as part of this study will be audio-recorded and these digital audio recordings will be stored securely on encrypted and password protected drives separate from any personal information held about you. All the audio recordings will be transcribed, and during this process identifiable information will be removed.



- Not all parents will be invited to take part, but if you do take part in one of these interviews you will receive a £10 voucher as a token of our thanks for your time.

## WHAT ARE THE BENEFITS FOR ME AND MY CHILD?

The NHS has paid for and approved this study because evidence suggests the treatment might work. We cannot promise that your child will benefit directly, but you will be helping research to improve future treatment for children with ear discharge.



## WHAT ARE THE RISKS FOR ME AND MY CHILD?

- As mentioned above, there are possible allergic reactions to the antibiotic drops or antibiotics taken by mouth, but the medicines are routinely prescribed in the UK and are considered safe to use for children.
- The advice to gently press on the outer ear flap to help the ear drops flow into the ear hole may cause discomfort to some children. If this happens, it is not necessary to continue using this “pumping” method but to simply keep your child’s head tilted to one side for a few extra minutes, to make sure the drops have reached the ear drum.

- The collection of the stool samples may prove to be a sensitive issue with your child or yourself, and therefore, the stool sample collection is optional. Your child's participation in the study will not be affected if a sample cannot be obtained.

## WHAT ELSE SHOULD I KNOW?

- Your child could receive antibiotic ear drops, delayed oral antibiotics or immediate oral antibiotics. We do not yet know whether using antibiotic eardrops is better than oral antibiotics or just in case antibiotics.
- You can still give your child painkillers. **Taking part in the study does not affect the care or treatment your child would normally receive from the doctor or nurse.**
- If your child is on other medication which stops them taking part in the study, the doctor or nurse will tell you.
- If you might be away on holiday or otherwise unavailable for us to reach you by telephone during the 14 day follow-up period, you might not be able to take part.
- If you have **any** problems completing the symptom questionnaire or giving the medicines, please do not worry that this will affect your child's participation in the study. You can contact the study team if you have any questions at all - please see contact details listed on the last page.

- Stool samples will be sent to Southmead Hospital (North Bristol NHS Trust) in a Post Office-safe box designed for the transport of material. This will be placed inside a biohazard bag, which fits requirements of the UN3373 regulations on transport of biological substances.

- The stool sample collected from your child will be tested for antibiotic resistance in E.coli (a common bug or microbe which is found in stools) and is only used for research purposes. Your doctor will not routinely receive any results of this test. In the unlikely event that a microbe is found that could affect the health of your child the lab will contact your GP.

- After the stool samples have been tested they will be kept at the laboratory for the duration of the study. If you have consented to your child's stool samples being used in future research related to microbes then the samples will be stored securely at the laboratory. If you have not consented to this, the samples will enter the normal disposal process.

- All participating GP practices will have their time compensated for participation in this study.



## WHAT HAPPENS TO MY CHILD'S AND MY OWN INFORMATION?

When you and your child are recruited to the study, the GP will use an online, secure software system called TRANSFoRm, to extract information from your child's medical records and enter information into the study research database.

You and your child's personal details which we use to contact you during the study follow-up period and to send out the 3-month stool sample kit and questionnaire, are transferred to a secure study administration database called REDCap at the University of Bristol.

The information you give us will be securely stored for 15 years after the trial ends, at the University of Bristol and protected in accordance with the University's guidelines and the Data Protection Act.

Personal details, e.g. names and addresses, will be stored separately to any other information you give us for this study and will be kept for a period of no more than 3 years after the trial ends. Only authorised and qualified staff will be able to look at the information. At the end of 3 years all of the identifiable information will be destroyed.

The findings of the study will be published in reports, scientific journals and presented at scientific conferences so that other people can learn from this research. Your information will be completely anonymous when this happens. Some quotes from the interviews may be published, but no names or other personal details will be used.

With your permission, data collected in this trial may be used in future ethically approved studies on the understanding that all shared information will be shared anonymously with other researchers. It will continue to be kept securely and remain confidential.

## WHAT HAPPENS IF I DECIDE NOT TO TAKE PART OR DON'T WANT TO CARRY ON?

It's entirely your choice whether to take part. If you decide not to take part or you opt out after having joined the study, your child will still receive their usual medical care for ear infection.

You can stop taking part in the study **at any time** by telling the doctor or nurse or letting the research study team know in the following ways:

Phone: [REDACTED] (there is an answerphone on this line)

Text: [REDACTED]

Email: [REDACTED]

Although it would be useful to know why, you do not have to give us any reason. We would like to use any information collected up until that point, unless you tell us you do not want any of your information to be used.

We would like to interview a few people who decide not to take part about their reasons. If you are happy to do this, a researcher will arrange a convenient time for a short (about 20 minutes) telephone interview and we will send you a £10 High Street voucher as a thank you.

## WHAT IF SOMETHING GOES WRONG?

In the unlikely event that something goes wrong please contact the study team and / or your local GP Surgery. Bristol University has taken out an insurance policy and if something goes wrong and it is related to taking part in the study, you may be eligible for compensation. This does not affect your statutory legal rights.



## WHO IS ORGANISING AND FUNDING THE STUDY?

The study is organised by researchers at the Universities of Bristol, Southampton and Imperial College London. The Research Directors are Professor Alastair Hay, University of Bristol ([REDACTED]) and Professor Michael Moore, University of Southampton ([REDACTED]).

This study has been funded by the National Institute for Health Research's Health Technology Assessment programme (# 16/85/01).

## WHO HAS REVIEWED THE STUDY?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the South Central - Oxford B Research Ethics Committee.

## CONTACT FOR FURTHER INFORMATION

If you require more information or wish to discuss the study further, please contact Kathryn Curtis, Study Manager, [REDACTED] / email: K[REDACTED]k or Sue Harris, Study Research Nurse, [REDACTED] (there is an answerphone on this line) / email: S[REDACTED]k.

## WHAT IF I WANT TO MAKE A COMPLAINT?

The Patient Advice and Liaison Service (PALS) can provide general advice about taking part in research. They can provide help and support with a range of queries. PALS can be contacted on 0117 900 3433 or pals@bristolpct.nhs.uk. If you wish to make a formal complaint please contact: Kat Tucker, Complaints and Freedom of Information Manager, NHS Bristol, South Plaza, Marlborough Street, Bristol, BS1 3NX or telephone: 0117 900 2494.



## THANK YOU FOR READING THIS

If you would like to take part or would like more information or advice  
please talk to the receptionist, doctor or nurse.



University of  
**BRISTOL**

UNIVERSITY OF  
**Southampton**



Bristol  
Randomised Trials  
Collaboration



the runny ear study

IRAS ID: 229293

Funded by



National Institute for  
Health Research

# the runny ear study

“Hello, I’m Karl.  
Sometimes my ear hurts  
and I need to see the doctor.”

If your child’s ear hurts, you can take part in new research  
to find a better way to treat ear infection. If your child is between

**12 months and 16 years,**

please ask your Nurse or GP to tell you more and how you can help.



# the runny ear study

## Re: Early Closure of the REST Study: Information for Parents

Thank you very much for your participation in the REST study. We would like to make you aware that the REST study will be closing earlier than originally planned due to lower than expected recruitment numbers. This is mainly due to problems with the study software. The study will now close at the end of March 2020.

### **We want to reassure you that there have not been any safety concerns raised.**

Due to this early closure, there have been some changes made to the study since your child was recruited. These changes have no impact on your child's participation in the study or any medical care they receive. However, the research team wish to keep you informed about the REST study.

The changes are:

- The parent information sheet states that we will be recruiting 400 participants. However, due to the early closure we will be recruiting fewer participants.
- The optional stool sample collection, as explained in the parent information sheet and summary parent information sheet is no longer being collected. Therefore, any future children recruited into the REST study will not be asked to collect this.
- The results we collect from existing participants will be used to inform the feasibility of other trials of this kind in the future.

Your child's participation in the REST study is important and will provide us with valuable information about running similar studies like this in the future.

Our intention is to send you a summary of the study results, once the main study report has been published.

If you have any queries, please do not hesitate to contact the team at: [REDACTED]

[REDACTED]

Yours sincerely

[REDACTED]

Professor Alastair Hay  
REST Co-Chief Investigator

[REDACTED]

Professor Michael Moore  
REST Co-Chief Investigator



IRAS ID: 229293



The Runny Ear Study is funded by the National Institute for Health Research's HTA Programme HTA 16/85/01