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Participant MAIN Information Sheet

An open randomised trial of the Arabin pessary to prevent preterm birth in twin pregnancy, with health economics and acceptability – STOPPIT-2

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The study aims to determine whether the Arabin cervical pessary prevents preterm birth in women with a twin pregnancy and a short cervix. Women with a twin pregnancy are at risk of having a baby preterm (before their due date). Women with a short cervix are at extra risk of a preterm birth. Babies born prematurely have increased risk of health problems and are more likely to require admission to the neonatal unit.

The Arabin cervical pessary is placed in the vagina and fits over the cervix. The pessary is made of silicone which is soft and flexible. Fitting the pessary involves minor discomfort only. The pessary is then left in place until 36 weeks of pregnancy but if the woman goes into labour it will be removed. Recent studies indicate the pessary may prevent preterm birth in twins. We want to find out if this is correct.

The study is in two parts:

The first is a SCREENING PHASE where we ask women to have an ultrasound scan of their cervix (neck of the womb) to measure its length. We hope that 2500 women will participate in this part of the study. If your cervix is found to be longer than 35mm in length you will continue with the standard treatment, which is planned for you by your clinical team.

The second part is a TREATMENT PHASE. Only women who have a short cervix (less than or equal to 35mm, about one third of women) will be asked to join in this phase. Women in the treatment phase of the study will be allocated at random to either standard treatment or standard treatment plus the Arabin cervical pessary. We will then compare the delivery outcomes and experience of the treatments, to see if the addition of the Arabin pessary reduces the risk of preterm birth. We hope that 500 women will participate in this phase of the study.

Why have I been asked to take part?

You have been asked to take part as you are pregnant with twins.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights. You may wish to discuss the study with your partner or other family members and we can provide you with additional information to share with them.

What will happen if I take part?

You will be given 24 hours to consider whether you wish to take part in the study; however you may wish to consent sooner than this. A member of the research team will ask you to sign a consent form which includes both the SCREENING and TREATMENT PHASES of the study.

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Screening phase

Once you have signed the consent form, you will be given a date and a time for an ultrasound scan to assess whether you have a short cervix (less than or equal to 35mm).

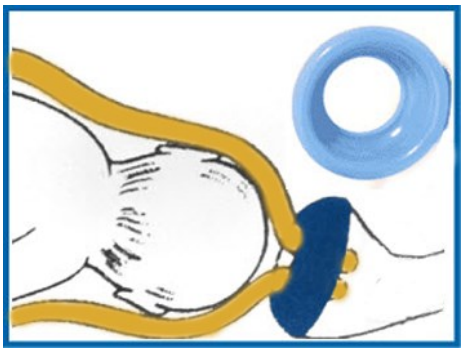
The ultrasound scan is performed using an ultrasound probe which is inserted into the vagina. It is no more uncomfortable than an internal examination. The scan will be performed between 18 weeks and 0 days and 20 weeks and 6 days of pregnancy. It may be possible to do this at the same time as the routine "fetal anomaly" scan. You will be told the results of this scan.

Treatment phase

If the scan shows that you have a short cervix (less than or equal to 35mm), you will be asked to reconfirm your intention to participate in the TREATMENT PHASE of the study. In this phase of the study, you will be randomised either to treatment with the Arabin pessary plus standard treatment, or to standard treatment alone.

If you are randomised to treatment with the Arabin pessary, the pessary will be inserted directly after the vaginal ultrasound scan. The pessary will be inserted before 21 weeks of pregnancy and it will remain in place until 36 weeks of pregnancy. The Arabin pessary will be in addition to the standard treatment that any woman pregnant with twins would have.

The Arabin cervical pessary is CE-marked for preventing spontaneous preterm birth. No modification to the device is required and the product will be used as per the CE certification and manufacturer's guidance. A diagram of the pessary and where it fits in the vagina is shown below. The midwife or doctor talking to you about the study will be able to show you what the pessary looks like.



If you are randomised to standard treatment, you will not have the Arabin pessary put in. You will have the standard treatment that any woman pregnant with twins would have.

Women with a cervix longer than 35 mm on scan

If you have a cervix that is longer than 35mm, you will not be suitable for randomisation or treatment with the Arabin pessary but you will continue to have the standard treatment, which any woman pregnant with twins would have.

Can I choose whether to have the pessary or not?

If you are suitable to be in the TREATMENT PHASE of the study we will allocate you to the pessary or to standard treatment at random. When we do not know which way of treating patients is best, we need to make a comparison. An important part of making a fair comparison is "randomisation". Most large trials are randomised. Patients taking part are randomly allocated either the standard treatment or the research treatment. This process is essential to avoid bias: if the groups receiving each treatment are the same, any differences in the results can only be down to the treatments. Therefore, randomisation means that the results are more reliable. The process of randomisation is usually carried out

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by a computer-based system. You will of course be told whether you have been randomised to the Arabin pessary or to standard treatment.

What information will be collected?

If you are in the **TREATMENT PHASE** of the study, we will arrange to contact you every 4 weeks. We will either see you at one of your routine clinic appointments or telephone you to see how you are. If you have the pessary fitted we will arrange an appointment to remove it around 36 weeks. After your babies are born we will collect some information from your notes and your babies' notes. We will use the information we collect to see whether the pessary improves the outcome of the pregnancy for both you and your babies. We will also ask you to fill in some questionnaires about your experience either by phone or by post.

If you are in the **SCREENING PHASE** of the study, you will continue with standard care. We will collect some information about the rest of your pregnancy (e.g. how many weeks pregnant you are when you have the babies, what your babies weigh etc) from you and your babies' medical notes. This will help us work out how well the cervical length scan predicts preterm birth.

In addition, we will ask all women who have consented if you are willing to discuss the possibility of being interviewed by a researcher. The researcher will initially speak to you and provide you with more information and if you are interested will send you written information and a consent form. If you agree, they will arrange an interview time suitable for you. The interview will be about your experience of the study; to find out what you think about the pessary and being in the trial. We will ask you to agree to these interviews being recorded. If you ask for the pessary to be removed, we may phone you to ask you to help us understand the reasons for this.

Is the cervical scan routine?

Having a cervical length scan is not routine in women with a twin pregnancy. So we will ask you to consent for this to be done as part of your inclusion in this research study.

What are the alternatives in preventing preterm delivery in twin pregnancies in women with a short cervix?

NICE (the National Institute for Health and Care Excellence) does not recommend any alternative treatments for women with a short cervix and a twin pregnancy. NICE publishes information for the public on how women with twin pregnancy should be managed at http://publications.nice.org.uk/antenatal-care-for-women-who-are-pregnant-with-twins-or-triplets-ifp129. The midwife or doctor looking after you can give you a printout of this if you wish.

What are the possible benefits of taking part?

There is evidence that the Arabin pessary helps prevent preterm birth. However, we cannot promise the study will directly help you or your babies. Information we obtain from your participation in the study may help inform on the future healthcare of other patients.

What are the possible disadvantages and risks of taking part?

You will have a transvaginal ultrasound during your routine antenatal visit and may then also have the pessary inserted. We will try to arrange for this to be combined with your scheduled antenatal appointments to minimise the inconvenience.

The transvaginal scan can be associated with some discomfort. In previous studies of the Arabin pessary, some women have experienced an increase in white vaginal discharge. The discharge does not smell. A small group of women may also feel the pessary inside the vagina. There may be some discomfort during pessary insertion or removal but women in the study overall found this tolerable and a simple process.

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What will happen if I don't want to carry on with the study?

You can withdraw from the study at any point. This would not affect your clinical care. However, if you have been fitted with a pessary, we would need to remove it at your convenience. We would hope to continue to collect some information from your notes about your health and your babies' health. We will discuss this with you but if you decide not to participate further the research team will collect this information from your notes unless you tell them (or another member of the clinical team) that you do not agree to this. We think this is important to collect this information, so that we can find out if the pessary does more good rather than harm.

What if there is a problem?

If you have a concern about any aspect of this study, you should speak with the researcher who will do their best to answer your questions. If you remain unhappy and wish to formally complain, you can do this through the NHS complaints procedure. Please contact:

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In the unlikely event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation (your local hospital or the study sponsors: University of Edinburgh/NHS Lothian) but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Will my taking part in the study be kept confidential?

Yes. In order to contact you about your own health your name and contact details will be accessed via your NHS records. Any details we have about you will be kept securely, with access restricted on a secure database managed by the University of Aberdeen. This information will be used only to contact you about the study by doctors or researchers running this trial. With your consent we will collect the following personal information: Ethnicity; Dates of Birth and Hospital number (NHS or CHI) for both you and your babies, The NHS number or Community Health Index number (in Scotland) is used for health care purposes and it uniquely identifies a person.

We will also collect your address: this is so we can contact you at the end of the study with information about the results. It may also be used to contact you again in the future, to see how you and your babies are doing. All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage. We will not share any personal information held about you with any other organisation. With your permission, we would like to share anonymised information with other researchers, so we can learn more about preterm birth in twins.

We will inform your GP that you are taking part, with your consent.

What will happen to the results of the study?

At the end of the study, we will be able to inform you of the study results if you wish. The results will be published in medical journals. You will not be identified in any report/publication. All information related to clinical studies in pregnancy is kept in secure storage for at least 25 years.

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Will you contact me in the future?

We may contact you again in the future to see how you and your babies are doing, and to ask if you are willing to help with follow up studies. This does not commit you to participate in any new studies, if you do not wish to. You will not be named or otherwise identified in any study publication.

Who is organising the research and why?

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Who should I contact?

If you are interested in participating in this study or would like further information, please contact:

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Thank you for taking the time to read this information sheet and for considering taking part.

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