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FOCUS Patient information Booklet (traditional format) for proxies Version 3.1 02/02/2016

1. Study Title

Fluoxetine Or Control Under Supervision (FOCUS) – a study to establish whether fluoxetine improves recovery after stroke.

2. Invitation paragraph

Your relative/friend is eligible to take part in a research study. Because he/she is unable to decide for themselves whether to take part, you are invited to decide on their behalf. Before you decide whether he/she will 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 e.g. your relatives or other health care professionals.

- Part 1 of this information sheet tells you the purpose of this study and what will happen to your relative/friend if he/she takes part.
- Part 2 gives you more detail about how the study is run.

Ask 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 your relative/friend to take part.

Thank you for reading this.

3. What is the purpose of this study?

Strokes can cause weakness of arms and legs, problems with speech, eyesight and even with memory, concentration and fatigue. Although these problems often improve after a stroke, many people will have long-term problems.

The FOCUS study aims to find out whether a drug called Fluoxetine improves patients' recovery so that they have fewer long-term problems. Fluoxetine is manufactured by several different companies which use their own trade names e.g. Prozac, Sarafem.

Fluoxetine has been used for many years to treat people with depression. However, small studies have suggested that it might also improve recovery after stroke by helping the brain repair itself.

We want to find out whether patients given one fluoxetine capsule each day for six months after a stroke recover better than those given a placebo (or dummy) capsule.
This study will recruit at least 3000 patients in stroke units and clinics from all over the UK. If effective, fluoxetine could become part of routine stroke care.

4. Why has your relative/friend been invited to take part?

Your relative/friend has been invited to take part because he/she recently had a stroke and currently has some ongoing stroke-related problems.

5. Do I have to take part?

It is up to you to decide whether he/she will take part or not. If you decide he/she will take part, you will be given this information booklet to keep and be asked to sign a consent form. If you decide he/she will take part, you are still free to ask that he/she stops taking the study capsules if you wish, or to withdraw him/her completely from the study at any time and without giving a reason. A decision to withdraw, or not to take part, will not affect the care he/she receives.

6. What will happen to him/her if he/she takes part?

A member of the research team will collect some information about his/her medical condition from his/her notes, ask you some simple questions, record his/her home address and telephone numbers, and those of his/her next of kin or other close personal contacts, so that the study team can contact you later to find out how he/she is doing.
The research team will enter this information into a computer, which will then randomly allocate him/her to take either fluoxetine, or a 'dummy' capsule. Half the patients in the study will receive the 'dummy' capsule and half will receive the fluoxetine capsule.

The two capsules look identical, so neither your relative/friend, you, nor his/her doctors or nurses, will know whether he/she is receiving the fluoxetine capsule or the dummy capsule. He/she will be asked to take the capsule once a day for 6 months. If he/she cannot swallow the capsules and has a feeding tube, the contents of the capsule will be put down his/her tube. Fluoxetine has few side effects. Most of these are not serious. Part 2 describes them. If he/she develops any symptoms which you think might be due to the capsules, you should inform the doctors or nurses responsible for his/her care.

<u>First follow-up assessment</u>

When he/she leaves the stroke unit or moves to a rehabilitation unit, information about how he/she is, will be collected from his/her medical notes.

If he/she required only out-patient treatment for his/her stroke, the trial office will contact him/her and his/her general practitioner at one month to find out whether he/she is still taking the trial medication, whether he/she has had any side effects, and whether he/she has been started on any other medication

We will write to him/her at three months to provide him/her with an opportunity to tell us how things are going, whether he/she is taking the trial capsules, and whether he/she has had any side effects.

Assessment at 6 months after his/her stroke

We will contact his/her general practitioner (GP) to find if he/she is still taking the capsules, whether he/she has had any side effects and whether he/she has been started on any other medications. The trial team will write to him/her, and ask him/her to complete a questionnaire about how he/she has been getting on since his/her stroke.

He/she will return the completed questionnaire in a freepost envelope or enter this information on line via a personal computer linked to the internet. If we don't hear from him/her, one of our research team in Edinburgh will contact him/her by telephone. If we cannot contact him/her we will contact his/her next of kin.

After the 6-month assessment, the study capsules will be stopped. He/she will return any unused capsules to us. He/she may do this by post or. Postal costs will be covered by the study.

Assessment at 12 months after his/her stroke.
We will check with his/her GP and then contact him/her again by post or telephone. We will ask him/her to complete the same questionnaire as he/she completed at 6 months.
This will allow us to find out whether any benefit from the fluoxetine continues after it has been stopped.

7. What happens after the 12-month assessment?

After the 12-month assessment, we will not contact him/her again. In the longer term, we would like to know how he/she is doing. The Health and Social Care Information Centre and other National Health Service bodies in the UK holds health information, such as hospital admissions, and we would like to use this routinely collected health data to tell us how he/she is doing.

8. What are the possible benefits of taking part?

If he/she is prescribed the fluoxetine, and the study shows that it improves recovery after stroke, he/she may have benefited directly from taking part.

Some patients find it helpful to be part of a research study and be under regular follow-up.

The results of the study will help us to treat future patients with stroke better.

9. What are the possible disadvantages and risks of taking part?

Apart from the possible inconvenience of the researcher taking up some of his/her time, we do not envisage any particular risks from his/her taking part. There are sometimes side effects from fluoxetine, but these are uncommon and are generally mild (see part 2). If any of his/her doctors think he/she would benefit from an antidepressant whilst he/she is in the study they will be able to use one that is compatible with the study medication.

10. What happens when the study stops?

We would like to provide him/her and you with regular updates on how the study is going, including the final results of the study. If you wish to receive these you can provide us with any email addresses (his/hers, your own). We will also put the trial results on our trial website.

11. What if there is a problem?

Any complaint about the way he/she/you have been dealt with during the study or any possible harm he/she might suffer will be addressed. Part 2 describe this in detail.

12. Will his/her taking part in the study be kept confidential?

Yes. All personal information will be kept confidential (see part 2).

13. Contact Details:

For further information, or if you have any concerns please contact Professor Martin Dennis, who is leading the study. He can be contacted through the FOCUS trial Helpline 0131 242 7741.

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering whether your relative/friend will take part, please read the additional information in Part 2 before making any decision.

Part 2

14. What if relevant new information becomes available?

If new information becomes available which might influence whether he/she should continue to take part in the study, we will contact them

15. What will happen if he/she don't want to carry on with the study?

He/she can withdraw from the study at any time. However, if he/she decides to withdraw, we would like to keep the information we have already collected about him/her.

If he/she stops taking the study capsules, we would still like to keep him/her in the study and follow him/her up.

16. What if there is a problem?

If he/she/you has a complaint about his/her treatment by members of staff (doctors, nurses etc), he/she/you should complain through the usual NHS complaints system.

If he/she/you has a complaint about the FOCUS study, he/she/you should contact Professor Dennis. If a serious adverse event occurs, it will be reported to the sponsor of the study (NHS Lothian and University of Edinburgh).

17. Will his/her taking part in this study be kept confidential?

Our procedures for handling, processing, storage and destruction of medical data are compliant with the Data Protection Act 1998.

We will obtain his/her/your permission to access his/her medical records and to collect data about him/her from The Health and Social Care Information Centre and other central UK NHS bodies during the course of the study and in the longer term.

Data about him/her will be stored on a secure computer database. The research team will be authorized to have access to the information.

The sponsors of the research (University of Edinburgh and NHS Lothian), and regulatory authorities will have access, as necessary, to view the information for monitoring the quality of research. All have a duty of confidentiality to him/her as a research participant.

He/she/you have the right to check the accuracy of information held about him/her and correct any errors.

18. Involvement of the General Practitioner/Family doctor (GP)

His/her own general practitioner will be informed about him/her taking part in the study.
His/her general practitioner will be asked to report to the trial team any adverse effects that he/she experience as a result of participating in the trial.

19. Will any blood, genetic tests or X Rays be done as part of the study?

No, the study does not involve any extra tests.

20. What will happen to the results of the research study?

The results of the study will be published in medical journals. We will also send a report to the funders of the study. No individual patient will be identified in these reports.

21. Who is organising and funding the research?

The University of Edinburgh and NHS Lothian are co-sponsors of the research and are overseeing it. Professor Dennis and Professor Mead are in charge of the study. They are not being paid for including your relative/friend. The Stroke Association and Health Technology Assessment is funding the study

22. Who has reviewed the study?

The Scottish Multicentre Research Ethics Committee has approved this study for conduct in the NHS (or private sector).

23. What are the possible adverse reactions to fluoxetine?

Fluoxetine has been extensively tested in clinical trials in patients with depression. It has been shown to be reasonably safe and well tolerated over many years.

It has been widely used to treat mood disorders in stroke survivors. In previous stroke studies indigestion, loss of appetite and sleep disturbance have been more common amongst those taking fluoxetine than placebo medication.

Over the page, we have listed all the side effects that have ever been noted. Everyone's reaction to a medicine is different. It is difficult to predict which, if any, side-effects he/she might have from taking a particular medicine.

The list of side-effects looks worrying. A small number are serious but the majority cause only minor inconvenience and will wear off over a couple of weeks as your body gets used to the medication. If the medication is stopped, the side effects will also wear off. It is important to have this whole list, though, so he/she/you can recognise side-effects if they happen.

If he/she does suffer symptoms that you think might be related to the trial medication, please mention this to his/her hospital doctor (if he/she is still an inpatient) or to his/her general practitioner, or contact the trial team.

All the side effects of fluoxetine that have ever been noted

The following side effects have been described, but their frequency is unknown.

- drop in blood pressure on standing or sitting up
- abnormal muscle movements such as twitches, tremors or jerks; balance or coordination problems; bruising and other bleeding problems
- blurred vision or eyesight problems
- feeling anxious, nervous or agitated; panic attacks, dizziness, drowsiness, tiredness, sleepiness, yawning, restlessness and inability to sit still, hallucinations, abnormal dreams, concentration problems; confusion depersonalisation or unusual thoughts, euphoria, mania or mania-like behaviour
- dry mouth, loss of appetite, weight loss, nausea, vomiting, indigestion, swallowing difficulties or bad taste in the mouth, diarrhoea
- hypersensitivity or allergic reactions – swelling of the face or tongue, or anaphylactic reaction
- skin rashes: urticaria, itching, ulceration of the mouth, sore throat, hair loss, light sensitivity
- chills, sweating, production of breast milk

- not being able to pass urine or urinating more often
- abnormal laboratory test results, liver problems, breathing difficulties, lung problems, metabolic problems, blood sugar control changes in diabetics
- headaches, joint pain, bone fractures, muscle pain or tenderness
- seizures
- abnormally high body temperature, rigidity, muscle twitches or sudden jerks, mental changes including confusion, irritability, agitation, delirium or coma. These symptoms in combination might suggest a very rare complication called the serotonin or neuroleptic malignant-type syndrome - this may be fatal. You or your carer must seek immediate medical help if you get these symptoms
- sexual dysfunction including delayed or absent ejaculation or difficulty achieving an orgasm
- thoughts of committing suicide or suicidal tendencies – the risk of this is extremely low. It is slightly more common in depressed adolescents than in older people with depression
- withdrawal symptoms can occur when this medicine is stopped abruptly. These include dizziness, sensory changes such as tingling feelings, weakness, increased agitation, anxiety, sleeping problems including sleep disturbances or intense dreams, nausea, vomiting, tremors or headaches.