

Fluoxetine Or Control Under Supervision (FOCUS) trial: to establish the effect(s) of routine administration of Fluoxetine in patients with a recent stroke

Submission date 16/05/2012	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 23/05/2012	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 27/05/2020	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Fluoxetine is an effective and safe drug which has been successfully used for many years to relieve depression. There is now also evidence from small trials that fluoxetine might have other effects on the brain e.g. generation of new brain cells, which might help patients make a better recovery from the physical effects of their stroke. For example, a recent small trial from France suggested that fluoxetine might improve the recovery of strength in stroke patients with residual arm weakness. The aim of this trial is to find out whether fluoxetine, given for 6 months, improves recovery if started in stroke patients who are between 2 and 15 days after their stroke.

Who can participate?

Stroke patients who had a stroke between 2 and 15 days previously can participate, providing they are at least 18 years of age, have had a brain scan that is compatible with a stroke (either due to a bleed or a blood clot in the brain), and still have some residual problems caused by the stroke e.g. weakness in the arm or leg. Stroke patients cannot participate if they are taking medication that might interact with fluoxetine, e.g. a selective serotonin reuptake inhibitor (a type of antidepressant), or if they have had seizures in the past or if they are seriously ill with other medical problems.

What does the study involve?

Researchers will collect information about the type of stroke the patients have had. Then, half the patients will be randomly allocated to fluoxetine capsules for 6 months, and the other half to an identical 'placebo' capsule for 6 months. At hospital discharge, or at 1 month for patients who did not require hospital admission, the researchers will check whether participants are still taking the trial capsules and whether they have experienced any adverse effects. At 3 months, the researchers will contact the participants to check whether they are still taking the capsules, and ask about adverse effects. At six and 12 months after recruitment, participants will be asked to complete questionnaires about their overall recovery from the stroke, and about common problems after stroke e.g. weakness in limbs, memory problems, problems with speech, low

mood. These questionnaires can be completed on paper, via the secure trial website or by telephone. If patients cannot complete the forms themselves, their next of kin or carer will be asked to do this. General practitioners will also be contacted at 6 months and 12 months to enquire about any medical problems and use of health care resources e.g. attendance at hospital, new medications. Patients' involvement will end 12 months after recruitment. The researchers will collect data on long-term recovery through national statistics.

What are the possible benefits and risks of participating?

If fluoxetine improves recovery from stroke, those patients allocated fluoxetine may have benefited. However, fluoxetine may have side effects and it may not improve recovery from stroke.

Where is the study run from?

University of Edinburgh and NHS Lothian (UK)

When is the study starting and how long is it expected to run for?

The study will start recruiting patients in July 2012, and will recruit for about four years. Patients will be followed up for 1 year. The study is likely to end in October 2017.

Who is funding the study?

The Stroke Association (UK)

Who is the main contact?

Dr Gillian Mead

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Contact information

Type(s)

Scientific

Contact name

Dr Gillian Mead

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

2011-005616-29

Protocol serial number

FOCUS2012

Study information

Scientific Title

Fluoxetine Or Control Under Supervision (FOCUS): a multicentre randomised trial to establish the effect(s) of routine administration of Fluoxetine in patients with a recent stroke

Acronym

FOCUS

Study objectives

The routine administration of fluoxetine (20 mg daily) for 6 months after an acute stroke will improve patients' functional outcome.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Scotland A Research Ethics Committee, 21/12/2011, ref: 11/SS/0100

Primary study design

Interventional

Study design

Multicentre parallel-group double-blind placebo-controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Ischaemic or haemorrhagic stroke

Interventions

Fluoxetine 20 mg once daily or matching placebo capsules for 6 months.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Fluoxetine

Primary outcome(s)

Modified Rankin scale at 6 months

Key secondary outcome(s)

1. Deaths from all causes at 6 and 12 months
2. Modified Rankin scale at 12 months
3. Stroke Impact Scale

4. Euroquol 5D-5L
5. Mental Health Inventory 5
6. Vitality subscale of SF36 (as an assessment of fatigue)
7. Diagnosis of depression
8. Other adverse events
9. Adherence to the trial medication
10. Health and social care resources used during follow up

Completion date

01/10/2017

Eligibility

Key inclusion criteria

1. Age > 18 years
2. Brain imaging is compatible with intracerebral haemorrhage or ischaemic stroke
3. Randomisation can be performed between 2 and 15 days after stroke onset
4. Persisting focal neurological deficit is present at the time of randomisation severe enough to warrant 6 months trial treatment from the patient's or carer's perspective

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

3127

Key exclusion criteria

1. Subarachnoid haemorrhage
2. Unlikely to be available for follow up at 12 months
3. Patient and/or carer unable to understand spoken or written English
4. Other life-threatening illness
5. Pregnant or breast-feeding or of child bearing age not taking contraception
6. History of epileptic seizures
7. Attempted suicide or self-harm
8. Allergy or contra indication to fluoxetine
9. Taken a monoamine oxidase inhibitor in last 5 weeks
10. Current or recent depression requiring treatment with selective serotonin reuptake inhibitor
11. Already participating in a Clinical Trial of an Investigational Medical Product

Date of first enrolment

01/07/2012

Date of final enrolment

31/03/2017

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

Royal Infirmary

Edinburgh

United Kingdom

EH16 4SA

Sponsor information

Organisation

University of Edinburgh and NHS Lothian (UK)

ROR

<https://ror.org/03q82t418>

Funder(s)

Funder type

Charity

Funder Name

Stroke Association ref: TSA 2011101

Alternative Name(s)

TheStrokeAssociation, TheStrokeAssoc

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/01/2019		Yes	No
Results article	results	01/05/2020	27/05/2020	Yes	No
Protocol article	protocol	20/08/2015		Yes	No
HRA research summary			28/06/2023	No	No
Other publications	statistical and health economic analysis plan	28/12/2017		Yes	No
Other publications	exploratory analyses	01/11/2019	01/04/2020	Yes	No