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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

Registration date
23/05/2012

Overall study status
Completed

Last Edited
27/05/2020

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number
2011-005616-29

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Multicentre parallel-group double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

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 measure
Modified Rankin scale at 6 months

Secondary outcome measures
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

Overall study start date
01/07/2012

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

3000

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
Scotland

United Kingdom

Study participating centre
Royal Infirmary
Edinburgh
United Kingdom
EH16 4SA

Sponsor information

Organisation
University of Edinburgh and NHS Lothian (UK)

Sponsor details
c/co Marise Bucukoglu
ACCORD

The Queens Medical Research Institute
47 Little France Crescent
Edinburgh
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United Kingdom
EH16 4TJ

Sponsor type
University/education

Website
http://www.accord.ed.ac.uk

ROR
https://ror.org/03q82t418

Funder(s)

Funder type
Charity

Funder Name
Stroke Association ref: TSA 2011101

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal and announcement of results at the UK stroke forum meeting.

Intention to publish date
31/12/2018

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?
Protocol article	protocol	20/08/2015		Yes	No
Other publications	statistical and health economic analysis plan	28/12/2017		Yes	No
Results article	results	19/01/2019		Yes	No
Other publications	exploratory analyses	01/11/2019	01/04/2020	Yes	No
Results article	results	01/05/2020	27/05/2020	Yes	No
HRA research summary			28/06/2023	No	No