

# Stem cell trial of recovery enhancement after stroke 3

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<b>Registration date</b> 08/12/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/09/2016	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

When someone has a stroke permanent brain damage can occur and result in long term disability. At present there is no treatment that improves long-term recovery in people who have had a stroke and are left with disability at least three months after the stroke. It is unclear whether treatment with drugs or rehabilitation therapy at this stage would improve recovery further. Laboratory work suggests that transplantation of stem cells (cells able to re-grow and change into different cell types) can improve recovery after stroke, possibly by helping the brain to replace lost cells. Bone marrow stem cells can be released into the blood stream following injection of a drug called granulocyte-colony stimulating factor (G-CSF). G-CSF has been tested early (in the first few days) after stroke but has not been given later after stroke. We want to test whether it is possible to give a drug (G-CSF) with a course of rehabilitation therapy (such as physiotherapy, PT; or occupational therapy, OT) to people at least three months after stroke. We hope that we will be able to show that giving the drug and the rehabilitation therapy will be possible, and may reduce disability after a stroke.

### Who can participate?

Adults (18 years and over, male and female), who have had a recent stroke (90 days to 1 year) with leg or arm weakness, who are no longer having rehabilitation therapy.

### What does the study involve?

Involvement in the study will last for 90 days. There will be three clinic appointments Day 0, Day 45 and Day 90. At these appointments participants will have assessments: some assessing mobility and physical ability and others assessing mental health, mental ability and ability to function in everyday society. There will also be some medical assessments looking at general health. Participants will be randomly allocated to four treatment groups (a computer will carry out the randomisation which is like tossing a coin):

G-CSF/No Rehabilitation Therapy

G-CSF/Rehabilitation Therapy

Dummy Drug/No Rehabilitation Therapy

Dummy Drug/Rehabilitation Therapy

A nurse will visit the participants at home to administer the drug in the form of an injection in the fatty layer of the skin for five days and will monitor for signs of side effects of the treatment

and document this. If the participant is to receive rehabilitation therapy they will receive 3 visits a week for 6 weeks. There will be a blood test on the first visit to clinic, and the last day of G-CSF treatment. The first blood test will give a baseline result for blood counts the second will look at substances in the blood that can help tell the effect the drug G-CSF has on the blood. The clinic appointments should last no longer than an hour and a half.

What are the possible benefits and risks of participating?

All drugs may have side effects. The side effects from G-CSF are generally mild. They can include muscle aches and pains, bone pain and dizziness. Bone pain is the most common side effect and can occur in approximately 10-20% of people receiving the G-CSF, however this is usually mild and can be treated with simple pain killers, such as paracetamol. Very rarely can G-CSF cause allergic reactions and temporary enlargement of the spleen, a part of the body that responds to the increase in bone marrow cells. It can also alter blood counts. This is why participants will have blood tests and regular monitoring during the study and if necessary the G-CSF will be discontinued. Participants will be asked to report any side effects to the research nurse. Participation in the study may reduce the symptoms of stroke or improve long-term recovery. The information we get from participants involvement may benefit other people who may have a stroke in the future.

Where is the study run from?

University of Nottingham (UK)

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

November 2011 to November 2013

Who is funding the study?

National Institute for Health Research (NIHR)

Who is the main contact?

Dr Nikola Sprigg

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## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**Protocol serial number**

## Study information

### Scientific Title

Stem cell Trial of recovery EnhanceMent after Stroke 3: a randomised controlled trial

### Acronym

STEMS3

### Study objectives

Many patients are left with longstanding (chronic) disability after stroke. Despite this most patients receive no therapy beyond the first three to six months after stroke. It is unclear whether treatment with drugs or rehabilitation at this stage would improve recovery further.

Experiments in animals suggest that transplantation of stem cells (cells able to regrow and change into different cell types) can improve recovery after stroke, possibly by helping the brain to replace lost cells. Bone marrow stem cells can be released into the blood stream following injection of a drug called granulocyte colony stimulating factor (GCSF).

GCSF has been tested early after stroke but has not been given to patients later after stroke.

The trial design will allow us to look at the effect of GCSF and therapy in chronic stroke, and to see if the two treatments work better when given together. The results will help in the design of further trials in chronic stroke.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Yorkshire and the Humber - Leeds East, 20/06/2011, ref: 11/YH/0138

### Study design

Randomised interventional treatment trial

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Topic: Stroke Research Network; Subtopic: Rehabilitation; Disease: Community study

### Interventions

We will perform a trial testing both GCSF, and a course of therapy given to 60 patients who have disability at least 3 months after their stroke. The patients will be living in the community, and will be visited by the research team to be assessed for enrolment in the trial. After consent into the trial, the research nurse will give GCSF or dummy as an injection under the skin for 5 days. Following this, patients will receive therapy from trial staff for 45 minutes three times a week,

for six weeks. The type and content of therapy will be dependent on the patients needs. Six weeks later the patient will be reassessed to see if there has been any change or improvement in their function.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Granulocytecolony stimulating factor

### **Primary outcome(s)**

1. Feasibility
2. Proportion of participants receiving all 5 GCSF/ placebo injections
3. Proportion of participants receiving all 18 therapy sessions

### **Key secondary outcome(s)**

1. Acceptability
2. Proportion of participants screened who are eligible for enrollment who give consent
3. Tolerability
4. Adverse events (headache, backache) reported after G-CSF administration
5. Secondary Haematological (FBC, WCC, CD34, PLT)
6. Post therapy intervention (day 45 and, end of follow-up day 90):
  - 6.1. Motor function (RMA)
  - 6.2. Change in dependency (modified Rankin Scale shift)
  - 6.3. Change in disability (change in BI)
  - 6.4. Quality of life (EuroQoL)
  - 6.5. Care giver burden

### **Completion date**

31/10/2013

## **Eligibility**

### **Key inclusion criteria**

1. Adults (18 years and over)
2. Male and female participants
3. Motor impairment (arm or leg) with residual disability (modified Rankin Score >1) due to stroke >90 days post onset.

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Lack of residual motor deficit
2. Significant cognitive impairment that will impede ability to complete assessments
3. Diagnosis likely to interfere with outcome or rehabilitation (e.g. terminal illness)
4. Still receiving post stroke rehabilitation
5. Pregnancy
6. Other exclusions of GCSF (as per British National Formulary)

**Date of first enrolment**

01/11/2011

**Date of final enrolment**

31/10/2013

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**University of Nottingham**

Nottingham

United Kingdom

NG7 2RD

**Sponsor information****Organisation**

University of Nottingham (UK)

**ROR**

<https://ror.org/01ee9ar58>

**Funder(s)**

**Funder type**  
Government

**Funder Name**  
NIHR Research for Patient Benefit, ref: PB-PG-0909-19113 (UK)

## Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**  
Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	09/09/2016		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No