

'Stem cell Trial of recovery EnhanceMent after Stroke 2' (STEMS2): pilot randomised placebo-controlled trial of granulocyte-colony stimulating factor in mobilising bone marrow stem cells in sub-acute stroke

Submission date 22/05/2006	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 07/11/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 16/08/2012	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Version 1.0

Study information

Scientific Title

Acronym

STEMS2

Study objectives

We hypothesise that Granulocyte Colony Stimulating Factor (G-CSF) mobilised Peripheral Blood Stem Cells (PBSCs) in patients with recent ischaemic stroke will migrate to the brain and promote recovery.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Nottingham LREC 1 on the 22nd May 2007 (ref: 07/Q2403/27).

Primary study design

Interventional

Study design

Randomised placebo controlled double blind and endpoint blinded trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Ischaemic stroke

Interventions

Subcutaneous human recombinant G-CSF (Filgrastim 1 x 10⁶ u/kg) versus saline started three to 30 days after stroke onset and given for five days.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Filgrastim

Primary outcome(s)

Number of patients having a serious adverse event by day 90.

Key secondary outcome(s)

1. Laboratory measures including CD34+ count
2. Clinical efficacy:
 - 2.1. Impairment
 - 2.2. Dependency disability

- 2.3. Functional independence
- 2.4. Quality of life
- 3. Length of stay in hospital, discharge disposition
- 4. Neuroimaging: including lesion size
- 5. Feasibility

Completion date

31/03/2010

Eligibility

Key inclusion criteria

- 1. Clinical stroke (lacunar or cortical)
- 2. Ischaemic or haemorrhagic type on neuro-imaging three to 30 days post-onset
- 3. Arm and/or leg weakness (Scandinavian Stroke Scale [SSS] arm and/or leg motor power less than six)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Prior to 09/09/09:

- 1. Pre-morbid dependency, modified Rankin Scale (mRS) more than three
- 2. Primary intracerebral haemorrhage
- 3. Dementia
- 4. Coma (SSS consciousness less than four)
- 5. Malignancy
- 6. Sickle cell disease
- 7. Pregnancy (see data sheet/British National Formulary [BNF] for other G-CSF contra-indications)
- 8. Known contra-indication to Magnetic Resonance Imaging (MRI)

Amended 09/09/09:

- 1. Pre-morbid dependency, modified Rankin Scale (mRS) more than three
- 2. Dementia
- 3. Coma (SSS consciousness less than four)
- 4. Malignancy
- 5. Sickle cell disease
- 6. Pregnancy (see data sheet/British National Formulary [BNF] for other G-CSF contra-indications)
- 7. Known contra-indication to Magnetic Resonance Imaging (MRI)

Date of first enrolment

02/07/2007

Date of final enrolment

31/03/2010

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Stroke Trials Unit

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

University of Nottingham (UK)

ROR

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

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK) - Grant application G0501997

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?
Results article	results	01/02/2012		Yes	No