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'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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/11/2006	**Overall study status** Completed	
Last Edited 16/08/2012	**Condition category** Circulatory System	

Plain English Summary
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1.0

Study information

Scientific Title

Acronym
STEMS2

Study hypothesis
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).

Study design
Randomised placebo controlled double blind and endpoint blinded trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Condition
Ischaemic stroke

Interventions
Subcutaneous human recombinant G-CSF (Filgrastrim 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)
Filgrastrim

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

Secondary outcome measures
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

Overall study start date
02/07/2007

Overall study end date
31/03/2010

Eligibility

Participant 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

Age group
Not Specified

Sex
Not Specified

Target number of participants
60

Participant 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)

Recruitment start date
02/07/2007

Recruitment end date
31/03/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Stroke Trials Unit
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
Nottingham City Hospital Campus
Hucknall Road
Nottingham
England

United Kingdom
NG5 1PB

Sponsor type
University/education

Website
http://www.nottingham.ac.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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