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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 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).

Study design
Randomised placebo controlled double blind and endpoint blinded trial

Primary study design
Interventional

Study type(s)
Treatment

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