

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

Submission date 26/08/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 31/10/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 20/12/2007	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 1.3 28/06/04

Study information

Scientific Title

Acronym

STEMS

Study objectives

Loss of motor function is common after stroke and often leads to significant long-term disability. Stem cells can be mobilised into the circulation using granulocyte-colony stimulating factor (G-CSF), an approach that has been found to be effective in experimental stroke. We aim to perform a pilot randomised placebo-controlled dose-escalation trial of G-CSF (1×10^5 - 3×10^6 μ /kg given once or once daily for 5 days, in dosing blocks: 1 dose or 5 doses 1×10^5 μ kg - 3×10^6 μ /kg, with level of 5 dose blocks depending on single dose data) in patients with motor weakness following ischaemic stroke, investigating its safety, feasibility of administration, tolerability, and effects on stem cell mobilisation, impairment, disability and dependency. The interaction between G-CSF and routine rehabilitation will be examined.

The study will last 24 months with 42 patients recruited over 19 months allowing 3 months follow-up. The results will help inform the design (inclusion criteria, outcomes, size) of further trials including the planning of a large definitive trial assessing the safety and efficacy (motor recovery and functional outcome) of G-CSF.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Nottingham Local Research Committee on the 5th June 2003 and had Medicines and Healthcare Products Regulatory Agency Clinical Trial Authorisation on the 10th March 2003).

Study design

Randomised placebo controlled pilot trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Stroke (ischaemic)

Interventions

Subcutaneous human recombinant G-CSF (filgrastim from Amgen) versus placebo.
G-CSF - 1×10^5 - 3×10^6 μ /kg given once or once daily for 5 days, in dosing blocks: 1 dose or 5 doses 1×10^5 μ /kg - 3×10^6 μ /kg, with level of 5 dose blocks depending on single dose data.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Circulating CD 34+ (flow cytometry) stem cells - aim greater than $10 \times 10^6/l$
2. Clinical safety: death, recurrent stroke, deterioration, palpable splenomegaly, at 10 days
3. Laboratory safety: white cell count (WCC, differential), platelet count (PC)

Key secondary outcome(s)

Clinical efficacy:

1. Impairment (SSS)
2. Disability (Barthel Index, [BI])
3. Dependency (mRS)
4. Cognition (Mini Mental State Examination [MMSE])
5. Depression (Zung)
6. Quality of life (EuroQOL)
7. Disposition (home, institution)

Outcomes measured at 10 and 90 days.

Completion date

01/08/2006

Eligibility

Key inclusion criteria

1. Clinical stroke (lacunar or cortical)
2. 7 - 30 days post-onset
3. Arm and/or leg weakness (Scandinavian Stroke Scale [SSS], arm and/or leg motor power less than 6)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Pre-morbid dependency, modified Rankin scale (mRS) greater than 3
2. Primary intracerebral haemorrhage
3. Dementia
4. Coma (SSS consciousness less than 4)
5. Malignancy
6. Sickle cell disease
7. Pregnancy

Date of first enrolment

01/08/2003

Date of final enrolment

01/08/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University of Nottingham

Nottingham

United Kingdom

NG5 1PB

Sponsor information

Organisation

University of Nottingham (UK)

ROR

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

Funder(s)

Funder type

Charity

Funder Name

The Stroke Association (UK) (ref: TSA 01/03)

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	01/12/2006		Yes	No