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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

Registration date
31/10/2005

Overall study status
Completed

Last Edited
20/12/2007

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 x 10^5 - 3 x 10^6 µ/kg given once or once daily for 5 days, in dosing blocks: 1 dose or 5 doses 1 x 10^5 µkg - 3 x 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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

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

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Circulating CD 34+ (flow cytometry) stem cells - aim greater than 10 x 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)

Secondary outcome measures
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 measurd at 10 and 90 days.

Overall study start date
01/08/2003

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

Age group
Adult

Sex
Both

Target number of participants
42

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
England

United Kingdom

Study participating centre
University of Nottingham
Nottingham
United Kingdom
NG5 1PB

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
Clinical Sciences Building
Nottingham City Hospital Campus

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England
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Sponsor type
University/education

Website
http://www.nottingham.ac.uk

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Charity

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

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	01/12/2006		Yes	No