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Erythropoeitin to facilitate stroke recovery

Submission date
20/09/2012

Recruitment status
Stopped

Registration date
27/11/2012

Overall study status
Stopped

Last Edited
27/01/2017

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Stroke affects nearly 100,000 people in the UK every year, and only half of all stroke survivors make a full recovery. Rehabilitation leads to improvements in many cases, but it is possible that other treatments can improve recovery even further. One such treatment is Erythropoietin (EPO), which is a purified artificially produced hormone that stimulates the growth of stem cells, especially in the bone marrow, which leads to an increase in the production of red blood cells. It also stimulates the growth of other stem cells involved in repair and some studies have suggested that it may increase brain repair in patients who have suffered stroke. EPO has been used routinely for several years to treat anaemia. The aim of this study is to find out if treatment with EPO, together with rehabilitation further improves recovery.

Who can participate?
Men and women aged between 18 and 85 years who are approached to take part within 48 hours of having a stroke, and do not already have a significant disability.

What does the study involve?
Eligible patients undergo a comprehensive MR imaging for blood flow, concentration of different chemicals and connections across the brain. Following this, patients are randomly allocated to one of three groups. The control group receive standard of care treatment with therapists and the rehabilitation team. The second group receive the drug erythropoietin (EPO) on three occasions injected into the vein on days 1, 3 and 5. The third group receive the drug rhEPO injected into the vein on days 7, 14 and 21. Patients are monitored for 1 week after the treatment with clinical examination and blood tests. The EPO injection is not given if blood tests show too much blood is being produced. Further analyses are made 30 and 90 days after being included in the study. A further MRI scan of the head is done to assess recovery.

What are the possible benefits and risks of participating?
A possible individual benefit of being treated with EPO cannot be stated at this point in time but the results of the study will contribute to a better public knowledge about the best treatment for rehabilitation after a stroke. Like most drugs, EPO could cause some side effects or an allergic reaction. The most common side effects include a rise in blood pressure, headache, nausea and joint pains which occur in about 1 in 10 patients especially at the start of treatment. About 1 in 100 patients show an increase in the number of platelets that can increase the risk of clots. Other side effects include diarrhoea, flu-like illness, rash, and vomiting which may occur in

1-2 in 100 patients. Allergic reactions are rare and include rash, itching, and very rarely swelling of the tongue and mouth.

Where is the study run from?
The study is run from Kings College Hospital NHS Foundation Trust and the Department of Clinical Neurosciences, Kings College London (UK)

When is the study starting and how long is it expected to run for?
November 2012 to May 2014

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof. Lalit Kalra
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10503

Study information

Scientific Title
Erythropoeitin to facilitate stroke recovery: a randomised trial

Study objectives
The research will show whether EPO treatment given early or late during stroke recovery has the potential to improve recovery in stroke patients who have not been thrombolysed. If EPO is shown to have the potential to influence brain repair, information from the study will be used to design larger definitive clinical trials for translation into clinical use in 35 years.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Westminster, 26/05/2011, ref:11/LO/0346

Study design
Randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
The research will be undertaken in three groups of 30 stroke patients each who are within 48 hours of stroke onset, have not been thrombolysed and have no contraindications to EPO treatment. All groups will receive best usual treatment consisting of structured multidisciplinary rehabilitation on a stroke unit. In addition, participants in the second group will receive EPO 40,000 IU given intravenously at 1, 3 and 5 days and those in the third group will receive EPO 40,000 IU/ given intravenously at 7, 14, 21 days. The differences in recovery between the groups will be assessed at 30 and 90 days after randomisation by measuring clinical recovery in function and changes in the brain perfusion and structure using magnetic resonance (MR) imaging.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Erythropoeitin

Primary outcome measure
Change in Fugl-Meyer scale score from baseline

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/11/2012

Completion date
31/05/2014

Reason abandoned (if study stopped)
Difficulties in recruitment and withdrawal of funding

Eligibility

Key inclusion criteria
1. Supratentorial ischaemic stroke, confirmed on imaging
2. Recruited within 48 hours of stroke onset. Time of onset is when symptoms began; for stroke that occurred during sleep, time of onset is when patient was last seen or was selfreported to be normal
3. NIHSS score 624 with NIHSS 1A (level of consciousness) score <2 at the time of enrolment
4. Reasonable expectation of availability to receive the full course of therapy, and to be available for subsequent follow-up visits
5. Reasonable expectation that patient will receive standard poststroke physical, occupational and speech therapy as indicated

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
UK Sample Size: 90

Key exclusion criteria
1. Prestroke modified Rankin Score (mRS) >2
2. Thrombolytic treatment with tPA following the index stroke
3. Patients presenting with hemorrhagic and/or brain stem stroke
4. Women who may be pregnant or breastfeeding
5. Serum hemoglobin > 16 g/dL (males) or > 14 g/dL (females), or platelet count > 400,000/mm3
6. Advanced liver, kidney, cardiac or pulmonary disease (serum bilirubin > 1.5 x upper limit of normal (ULN), Alkaline phosphatase > 2.5 x ULN, GGT>2.5xULN

7. History of clotting disorders
8. Expected survival < 1 year
9. Allergy or other contraindication to erythropoeitin as per SPMC
10. A known diagnosis of cancer (except nonmalignant skin cancer)
11. A known diagnosis of epilepsy
12. Uncontrolled hypertension (BP persistently > 220 mm Hg systolic or 120 mm Hg diastolic despite antihypertensive therapy)
13. Preexisting and active major psychiatric or other chronic neurological disease
14. Currently participating in another investigational study

Date of first enrolment
01/11/2012

Date of final enrolment
31/05/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College Hospital NHS Trust
London
United Kingdom
SE5 9PJ

Sponsor information

Organisation
King's College Hospital NHS Foundation Trust (UK)

Sponsor details
Neonatal intensive care unit (NICU)
Denmark Hill
London
England
United Kingdom
SE5 9RS

Sponsor type
Hospital/treatment centre

Website

http://www.kch.nhs.uk/

ROR
https://ror.org/01n0k5m85

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) - Central Commissioning Facility (UK)

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?
HRA research summary			28/06/2023	No	No