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Effect of erythropoietin on level of circulating endothelial progenitor cells and outcome in patients after acute ischaemic stroke

Submission date 23/11/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/01/2011	**Overall study status** Completed	
Last Edited 14/01/2016	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of erythropoietin on level of circulating endothelial progenitor cells and outcome in patients after acute ischaemic stroke: a prospective randomised placebo controlled trial

Study objectives
Erythropoietin (EPO) enhances circulating level of endothelial progenitor cells (EPCs) which has been reported to be associated with prognostic outcome in ischaemic stroke (IS) patients. This study aimed at evaluating the time course of circulating EPC level and the impact of EPO therapy on EPC level and clinical outcome in patients after acute IS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Chang Gung Memorial Hospital Research Ethics Committee, 30/01/2008, ref: 96-1381A

Study design
Prospective randomised placebo-controlled 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 contact han.gung@msa.hinet.net to request a patient information sheet

Health condition(s) or problem(s) studied
Acute ischaemic stroke

Interventions
Two consecutive doses of EPO (5,000 IU each time, subcutaneously) administered at 48 hours and 72 hours after acute IS.

Intervention Type
Other

Primary outcome measure
90-day combined major adverse neurological event (MANE) defined as:
1. Recurrent stroke

2. National Institutes of Health Stroke Scale (NIHSS) greater than or equal to 8
3. Death

Secondary outcome measures
To establish the time course of circulating level of EPCs in patients after acute IS and the ability of two doses of EPO in enhancing circulating EPC level

Overall study start date
01/10/2008

Completion date
31/12/2010

Eligibility

Key inclusion criteria
Patients aged greater than 45 years, either sex

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
220

Key exclusion criteria
Patients with history of the followings were excluded from the study:
1. Intracranial haemorrhage
2. Surgery or trauma within the preceding 3 months
3. Abnormal liver function
4. Haematology disorders
5. Renal insufficiency (serum creatinine greater than 1.5 mg/dL)
6. Malignancy
7. Febrile disorders
8. Acute or chronic inflammatory disease at study entry
9. Liver cirrhosis
10. Atrial fibrillation
11. Congestive heart failure
12. Contraindications for magnetic resonance imaging (MRI) examination
13. No evidence of acute IS by MRI study
14. Myeloproliferative disorder
15. Antibodies or being allergic to EPO
16. Pregnancy
17. Haemoglobin level greater than 15.0 g/dL

Date of first enrolment
01/10/2008

Date of final enrolment
01/03/2010

Locations

Countries of recruitment
Taiwan

Study participating centre
123, Ta Pei Road
Kaohsiung Hsien
Taiwan
83301

Sponsor information

Organisation
National Science Council (Taiwan)

Sponsor details
No. 106, HoPing E. Road
Sec.2
Taipei
Taiwan
10622

Sponsor type
Government

Website
http://web.nsc.gov.tw/

ROR
https://ror.org/02kv4zf79

Funder(s)

Funder type
Government

Funder Name
National Science Council (Taiwan) (ref: NSC-97-2314-B-182A-090-MY2)

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	25/02/2015		Yes	No