

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	<input type="checkbox"/> Prospectively registered
Registration date 10/01/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/01/2016	Condition category Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

Completion date

31/12/2010

Eligibility

Key inclusion criteria

Patients aged greater than 45 years, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

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Sponsor information

Organisation

National Science Council (Taiwan)

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

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