Interleukin-1 receptor antagonist in severe traumatic brain injury

Submission date 09/09/2008	Recruitment status No longer recruiting	Prospectively registered
		☐ Protocol
Registration date 24/11/2008	Overall study status Completed	Statistical analysis plan
		[X] Results
Last Edited	Condition category	Individual participant data
11/05/2016	Injury, Occupational Diseases, Poisoning	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

IL1ra 02 v04

Study information

Scientific Title

A single centre phase II study of interleukin-1 receptor antagonist in the treatment of severe traumatic brain injury

Study objectives

Interleukin-1 receptor antagonist (IL-1ra) is safe, will cross the blood brain barrier and attenuate the cerebral inflammatory response to traumatic brain injury.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cambridge Local Research Ethics Committee 2 (LREC 2), June 2008, ref: 06/Q0108/64

Study design

Open label randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Traumatic brain injury

Interventions

Participants are randomised to receive 5 days of 100 mg IL-1ra (Kineret) subcutaneously once a day or a placebo.

Clinical follow-up at 6 months.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Interleukin-1 receptor antagonist

Primary outcome(s)

Safety: based on adverse events, follow-up assessment of outcome at 6 months.

Key secondary outcome(s))

- 1. IL-1ra, IL-1alpha, IL-1beta, IL-6, IL-8 in serum and by cerebral microdialysis, measured by 4-hourly serum markers twice daily
- 2. Cerebral lactate, pyruvate, glucose, glutamate, glycerol by cerebral microdialysis, measured by 4-hourly serum markers twice daily
- 3. Clinical follow-up at 6 months, Glasgow Outcome Scale (GOS) and 36-item Short Form Health Survey (SF-36)

Completion date

15/09/2009

Eligibility

Key inclusion criteria

- 1. Severe traumatic brain injury
- 2. Aged 16 65 years, either sex
- 3. Abnormal computed tomography (CT) scan requiring sedation, paralysis, ventilation and multimodality monitoring as part of clinical care

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

- 1. Head injury unlikely to survive 5 days, e.g. bilaterally fixed dilated pupils
- 2. Follow up not possible
- 3. Not suitable for insertion of cranial access device, e.g. bleeding diathesis
- 4. Immunosuppression
- 5. Severe renal insufficiency
- 6. Pregnancy/nursing mothers
- 7. Known hypersensitivity to E. Coli derived products
- 8. Adminstration of live vaccine

Date of first enrolment

15/09/2008

Date of final enrolment

15/09/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Level 4 A block, box 167

Cambridge United Kingdom CB2 0QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust (UK)

ROR

https://ror.org/04v54gj93

Funder(s)

Funder type

Charity

Funder Name

Academy of Medical Sciences (UK)

Alternative Name(s)

The Academy of Medical Sciences

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Results article 01/05/2014 Yes No

Participant information sheet Participant information sheet 11/11/2025 No Yes