ISRCTN88597330 https://doi.org/10.1186/ISRCTN88597330

Interleukin-1 receptor antagonist in severe traumatic brain injury

Submission date	Recruitment status
09/09/2008	No longer recruiting
Registration date	**Overall study status**
24/11/2008	Completed
Last Edited	**Condition category**
11/05/2016	Injury, Occupational Diseases, Poisoning

[_] 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

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

Primary study design
Interventional

Study design
Open label randomised controlled trial

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 multi-modality 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	results	01/05/2014		Yes	No