ISRCTN74459797 https://doi.org/10.1186/ISRCTN74459797

A large simple placebo controlled trial, among adults with head injury and impaired consciousness, of the effects of corticosteroids on death and disability

Submission date
23/10/2000

Registration date
23/10/2000

Last Edited
11/07/2014

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[X] 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

Contact name
Dr Ian Roberts

Contact details
CRASH Co-ordinating Centre
Institute of Child Health
30 Guilford Street
London
United Kingdom
WC1N 1EH

Additional identifiers

Protocol serial number
G9722166

Study information

Scientific Title

Acronym
CRASH

Study objectives
The aim of the pilot phase was to determine whether a large-scale trial is feasible in the emergency setting, and to test and refine the study procedures for the main phase of the CRASH trial. The pilot phase was to be conducted over a one-year period.

The CRASH trial aims to determine reliably:
1. The effects of high dose corticosteroid infusion on death and on disability following significant head injury
2. The effects of such infusion on the risk of infection and of gastro-intestinal bleeding in this setting

Protocol can be found at: http://www.crash.lshtm.ac.uk/Trial_Protocol_English.html

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Placebo controlled trial

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Neuroscience, psychiatry

Interventions
1. Intervention: 48 hour infusion of methylprednisolone (MP) (0.4 g/h for 48 hours)
2. Control: placebo infusion

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Methylprednisolone

Primary outcome(s)

1. Death from any cause within two weeks of injury
2. Death or dependence at six months

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/12/2005

Eligibility

Key inclusion criteria
Head injured patients (judged to be 16 years or older) within 8 hours of injury who are not fully conscious (any abnormality on the Glasgow Coma Scale), except those for whom corticosteroids are thought to be clearly indicated or contra-indicated. There are no other pre-specified exclusion criteria, as the fundamental eligibility criterion is the responsible doctor's uncertainty whether or not to use corticosteroids in a particular adult with head injury.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/04/1999

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

CRASH Co-ordinating Centre
London
United Kingdom
WC1N 1EH

Sponsor information

Organisation
London School of Hygiene and Tropical Medicine (UK)

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/10/2004		Yes	No
Results article	results	01/06/2005		Yes	No
Protocol article	protocol	11/06/2001		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes