

# 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

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☒ Protocol

**Registration date**

23/10/2000

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

11/07/2014

**Condition category**

Injury, Occupational Diseases, Poisoning

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

**Study website**

<http://www.crash.lshtm.ac.uk/>

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Ian Roberts

**Contact details**

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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](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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Not Specified

**Participant information sheet**

Patient information can be found at: [http://www.crash.lshtm.ac.uk/TP\\_English\\_PatRelSheet.htm](http://www.crash.lshtm.ac.uk/TP_English_PatRelSheet.htm)

**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 measure**

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

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/04/1999

**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

**Age group**

Adult

**Sex**

Not Specified

**Target number of participants**

10000

**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**

England

United Kingdom

**Study participating centre**

**CRASH Co-ordinating Centre**

London

United Kingdom

WC1N 1EH

## **Sponsor information**

**Organisation**

London School of Hygiene and Tropical Medicine (UK)

**Sponsor details**

Keppel Street

London

England

United Kingdom

WC1E 7HT

+44 (0)20 7636 8636

**Sponsor type**

University/education

**Website**

<http://www.lshtm.ac.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, MRC

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# 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?
<a href="#">Protocol article</a>	protocol	11/06/2001		Yes	No
<a href="#">Results article</a>	results	01/10/2004		Yes	No
<a href="#">Results article</a>	results	01/06/2005		Yes	No