

Observation or computed tomography (CT) of mild head injury in Sweden. A randomised clinical trial concerning effects and costs

Submission date

27/08/2003

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

16/10/2003

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

25/09/2009

Condition category

Injury, Occupational Diseases, Poisoning

☐ Individual participant data

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

N/A

Study information

Scientific Title

Acronym

OCTOPUS study

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Mild head injury

Interventions

1. Admission for in-hospital observation
2. Urgent CT for all patients, early discharge if normal findings

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Study 1: Patient function at 3 months (Extended Glasgow Outcome Scale [GOSE]).

Study 2: Economic costs.

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/01/2004

Eligibility

Key inclusion criteria

2500 patients with mild head injury, defined as short-term loss of consciousness and/or amnesia as a result of head trauma. Upon presentation in the emergency department, the patient should have regained a normal level of consciousness as measured by the Glasgow Coma Scale (GCS 15) and have normal neurological findings.

Inclusion criteria:

1. Head trauma within the past 24 hours
2. Age 6 years or older
3. Confirmed or suspected amnesia or brief loss of consciousness
4. Normal neurological examination
5. No associated injuries that require admission

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

01/05/2001

Date of final enrolment

31/01/2004

Locations

Countries of recruitment

Sweden

Study participating centre

Octopus Trial Co-ordinator

Stockholm

Sweden

SE-171 76

Sponsor information

Organisation

Institution of Medicine, Karolinska Hospital (Sweden)

ROR

<https://ror.org/00m8d6786>

Funder(s)**Funder type**

Research council

Funder Name

All funding comes from public funds and peer-reviewed grants, including:

Funder Name

The Swedish Research Council

Funder Name

Expo/Stockholm County Council

Funder Name

The Vardal Foundation

Funder Name

The Health Research Council in the South-East of Sweden

Funder Name

Apoteket AB

Funder Name

The Swedish Society of Medicine

Funder Name

The Thelma Zoéga Foundation

Funder Name

Region Skåne

Funder Name

The Gorthon Foundation

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 on cost comparison | 02/09/2006 | | Yes | No |
| Results article | results on medical outcome | 02/09/2006 | | Yes | No |