ISRCTN81464462 https://doi.org/10.1186/ISRCTN81464462

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

Submission date	Recruitment status	[_] Prospectively registered
27/08/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/10/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/09/2009	Injury, Occupational Diseases, Poisoning	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Study 1: Patient function at 3 months (Extended Glasgow Outcome Scale [GOSE]).
Study 2: Economic costs.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/2001

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

Age group
Adult

Sex
Not Specified

Target number of participants
2,500

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)

Sponsor details
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Sponsor type
Hospital/treatment centre

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

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