European Society of Intensive Care Medicine study of therapeutic hypothermia (32-35 degrees Celsius) for ICP reduction after traumatic brain injury

Published: 19-03-2012
Last updated: 27-04-2024

The Eurotherm3235trial will examine the relationship between ICP reduction after TBI using therapeutichypothermia and patient outcome.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Increased intracranial pressure and hydrocephalus
Study type	Interventional

Summary

ID

NL-OMON38267

Source
ToetsingOnline

Brief title
EUROTHERM3235

Condition

- Increased intracranial pressure and hydrocephalus

Synonym
brain concussion, brain injury

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: European Society of Intensive Care Medicine

Intervention

Keyword: raised intracranial pressure (ICP), therapeutic hypothermia, traumatic brain injury

Outcome measures

Primary outcome

outcome at 6 months using the extended Glasgow Outcome Scale (GOSE)

questionnaire

Secondary outcome

6 month mortality rate, intracranial pressure control, incidence of pneumonia,

length of stay in hospital and ICU, Modified Oxford Handicap Scale score at one

month, discharge from randomising hospital or death whichever occurs first,

correlation betweenpredicted outcome using mOxford Handicap Scale at discharge

from hospital and the GOSE Score at 6 months and health economics

Study description

Background summary

Traumatic brain injury (TBI) is a major cause of death and severe disability throughout the world. TBI leads to 1,000,000 hospital admissions per annum throughout the European Union (EU). Ischaemia has a key role in all forms of brain injury and preventing ischaemic (or secondary) injury is at the core of all treatment strategies. The evidence from previous research shows that treatment with therapeutic hypothermia to reduce intracranial hypertension may improve patient outcome after TBI. Analysis has shown key relationships between length of hypothermia treatment and speed of re-warming with patient outcome. Improved patient outcome was found in the most recent meta-analysis when hypothermia was continued for between 48 hours and 5 days and patients were re-warmed slowly (1°C/4 hours). Experience with

cooling also appears to be important if complications which may outweigh the benefits of hypothermia are
to be avoided.

Study objective

The Eurotherm3235trial will examine the relationship between ICP reduction after TBI using therapeutic
hypothermia and patient outcome.

Study design

Prospective randomised controlled trial without blinding

Intervention

Therapeutic hypothermia between 32 and 35 degrees Celsius to lower ICP to below 20 mmHg

Study burden and risks

Potential adverse events of therapeutic hypothermia are well known, but on the other hand experience with this treatment at our ICU is extensive because this treatment is routinely applied at a very regular basis in every post cardiac arrest comatose patient. We monitor specific adverse events in the treatment group and a monitoring plan is available. This study is done because there may well be a beneficial effect overall on secondary brain injury with regard to functional outcome as well as mortality. Therefore we think that the benefits of therapeutic hypothermia may outweigh the adverse events.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
3015CE Rotterdam
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
3015CE Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1.18 years of age or older 2.primary closed traumatic brain injury 3.raised ICP>20mmHg 4. up to 10 days after initial head injury 5.cooling device or technique available for at least 48 hours 6.core temperature 36 degrees Celsius or higher at the time of randomisation 7.abnormal CT of the brain

Exclusion criteria

1.already receiving therapeutic hypothermia 2.barbiturate therapy prior to inclusion 3.unlikely to survive in next 24 hours according to ICU consultant or neurosurgeon 4.temperature 34 degrees or less at admission 5.pregnancy

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-03-2013
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	19-03-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-02-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-02-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	34555414
CCMO	NL35865.078.11