

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

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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Increased intracranial pressure and hydrocephalus
<b>Study type</b>	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 between predicted 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 Eurotherm3235 trial 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**

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## 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