Randomised evaluation of surgery with craniectomie for uncontrollable elevation of intra-cranial pressure

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders of the eye
Study type	Interventional

Summary

ID

NL-OMON33973

Source
ToetsingOnline

Brief title
RESCUEicp

Condition

- Neurological disorders of the eye

Synonym
intracranial pressure evelation

Research involving
Human

Sponsors and support

Primary sponsor: University of Cambridge
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: craniectomie, intra-cranial pressure, outcome

Outcome measures

Primary outcome

The primary endpoint will be assessment of outcome at discharge(Glasgow

outcome Score) and 6 months(Extended Goasgow outcome Score)

Secondary outcome

Secondary endpoints will be:

a. Assessment of outcome using the SF-36 and SF-10(for children below 16

years of age) questionnaires

b. Assessment of ICP control

c. Time in intensive care

d. Time to discharge from neurosurgical unit

e. Detailed health-economic analysis

Study description

Background summary

In patients with brain injury, cerebral ischaemia and brain swelling are the two main problems wchich occur generating a cascade of adverse metabolic events which culminate in a cycle of further swelling, reductions in blood flow and in oxygen and glucose supply. Therapy to reduce ICP following acute brain injury is the cornerstone to the management of these patients. The introduction of protocol driven therapy with a number of stages to reduce ICP has been one of the factors leading to potential improvements in outcome.
Two surgical manoeuvres can be employed to reduce ICP:

(1) The application of external ventricular drains to drain cerebro-spinal

fluid.

(2) Decompressive craniectomy (removal of a large area of skull with opening of the dura to increase the volume of the cranial cavity, facilitating a reduction in ICP).

Several reports in the literature investigate the role of decompressive craniectomy in traumatic brain injury . These studies demonstrated a wide range of clinical outcome, with no clear consensus regarding the indication for the operation. The generally accepted way to resolve the role of any therapy for neurotrauma is to obtain class I evidence by performing prospective randomised trials. Therefore a multi-centre European trial, co-ordinated by the University of Cambridge Department of Neurosurgery, in collaboration with the European Brain Injury Consortium (EBIC) has been started. This trial is designed for the following reasons:

1. Severe head injury is common and severe disability and persistent vegetative state has profound social and economic consequences

2. The current data (small studies, class II and III evidence, poor follow up) are inconclusive

3. A randomised study has the potential to address the concerns that the operation does not influence the favourable outcome of good prognosis patients and that it shifts outcome from death to vegetative state / severe disability in poor prognosis patients.

4. To establish the incidence of complications resulting from this procedure e.g. post-operative haematoma, infection.

Study objective

The aim of this trial is to determine the effectiveness of an operation (decompressive craniectomy), compared to medical management alone, to treat brain swelling and improve outcome. The results of this trial will better define the indications for treatment and the future management of these patients with traumatic brain injury.

Study design

The study will be a randomised trial comparing optimal medical management with surgery (decompressive craniectomy) for the management of intra-cranial hypertension following head injury, refractory to first-line treatment.

The trial will recruit from centres experienced in the intensive care

management of head injury. The target study group will be ventilated ICP-monitored patients with refractory intracranial hypertension. The two arms will be the continuation of optimal medical management versus surgery (decompressive craniectomy).

Intervention

(a) for unilateral hemisphere swelling / a large unilateral fronto-temporo-parietal craniectomy
or
(b) for bilateral diffuse hemisphere swelling a large bilateral fronto-temporo-parietal craniectomy from the frontal sinus anteriorly to the coronal suture posteriorly and pterion laterally with a wide dural opening (pedicles based on the superior sagittal sinus medially and division of the falx anteriorly).

If continued medical treatment is drawn no decompressive surgery will be performed and therapy with highdose barbiturates will started. Eventual decompressive surgery may be performed later at the clinician's discretion if the patient subsequently deteriorates (for example prolonged and unacceptably high ICP &gt40mm Hg with compromised CPP). This clause is required if a situation arises whereby the treating physician feels that withholding surgery is acting against the best interest of the individual - "the interests of the patient always prevails over those of science and society". The same principle applies to barbiturates in the decompressive craniectomy group.

Study burden and risks

As the patients who are included in the study are regarded as refractory intracranial pressure which means that ICP does not respond to the regular measures the outcome is expected to become fatal because of impending brain herniation and subsequent death. The associated risks of the craniotomy such as infection or haemorrhage in the operation area are normally low and seen in the light of the expected fatal outcome if medical treatment is withdrawn, neglectable.

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. Patients with head injury
2. age 18-65
3. Abnormal CT
4. ICP monitoring
5. refractory ICP to standard treatment for 1-12 hours

Exclusion criteria

Bilateral fixed and dilated pupils, bleeding diathesis, devastating injury not expected to survive for 24 hours, follow up not possible, patients treated on the Lund protocol, have recieved Barbiturates pre-randomisation, significant brain stem involvement on CT

Study design

Design

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):	01-01-2009
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL24833.042.08