

Decompressive Craniectomy for Post-traumatic Refractory Intracranial Hypertension: Update on the RESCUEicp Trial – www.rescueicp.com

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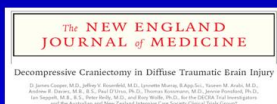


Introduction

Even though the last 15 years have seen a resurgence of interest in the use of decompressive craniectomy (DC) following TBI, there is still no consensus on if and when to proceed with the operation.

From 2002 to 2004, two multi-centre randomised trials started recruiting patients: the DECRA trial and the RESCUEicp trial.

Randomised trials of decompressive craniectomy for TBI



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| <ul style="list-style-type: none"> • RESCUEicp • 400 patients • Recruitment on-going • 10-65 years • Raised ICP refractory to protocol-based medical management • ICP threshold 25mmHg | <ul style="list-style-type: none"> • DECRA • 155 patients randomised • Completed • 15-60 years • Severe diffuse TBI within 72 hours post-injury • ICP threshold 20mmHg |
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The two trials have different hypotheses

RESCUEicp

Decompressive craniectomy can improve outcomes as a last-tier therapy for refractory post-traumatic intracranial hypertension

DECRA

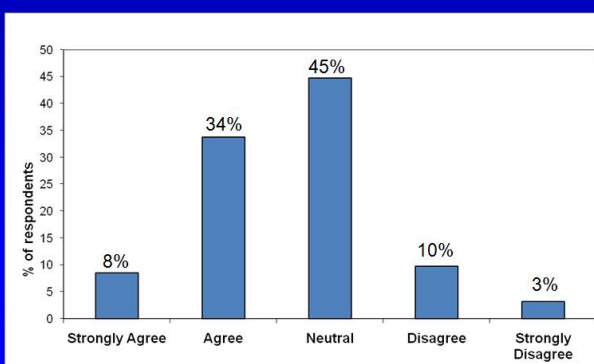
Early/neuroprotective bifrontal DC can improve outcomes following diffuse TBI

The DECRA study failed to show a clinical benefit with the use of early/neuroprotective decompressive craniectomy following diffuse TBI.

Decompressive craniectomy survey

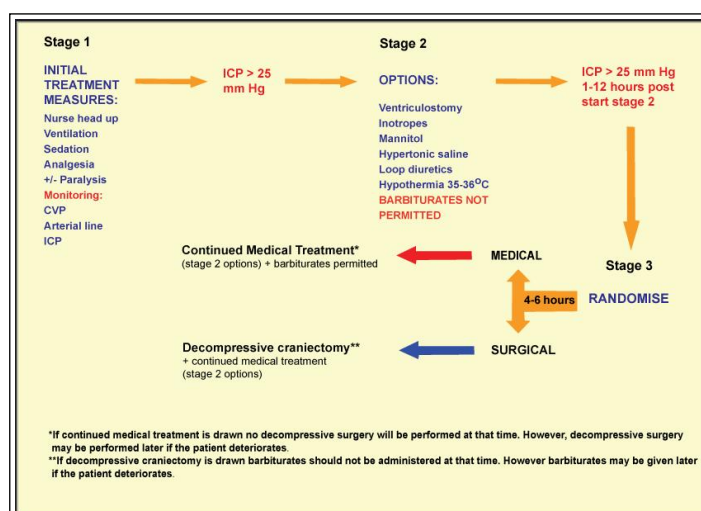
- 6 months after the publication of DECRA
- Participating societies [SBNS/BNTA, EANS, NeuroCritical Care Network (UK), Neurocritical Care Society (mainly USA)]

Do you think that decompressive craniectomy improves the long-term functional outcome of head-injured patients with refractory intracranial hypertension?
n = 503



Methods

The two arms of the RESCUEicp are continuation of optimal medical management (with barbiturates) versus surgery (unilateral or bifrontal DC).



Outcome is assessed using the extended Glasgow Outcome Scale and the SF-36 survey at 6, 12 and 24 months.

Results

The required sample size is 400 participants to detect a 15% difference in dichotomised outcome (power 80%, alpha 5%).

The study is ongoing and has now recruited **more than 85% of the required sample size**. Patients have been recruited from more than 40 units in 17 different countries.

UK centres have recruited 69% of the patients to date. **We are very keen to increase international contribution to RESCUEicp**. In the last few months, two US centres and four French centres gained the necessary regulatory approvals and have now joined RESCUEicp.

A trial extension until December 2014 was recently awarded to us; therefore, new sites are still welcome to join RESCUEicp.

Conclusions

DECRA and RESCUEicp have different hypotheses and inclusion criteria. Hence the DECRA results should not deter recruitment into RESCUEicp.

On the other hand, the DECRA results emphasize the fact that DC remains an unproven therapy, which should ideally be undertaken in the context of randomised trials.

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