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Optic nerve sonography in the non-invasive assessment of severe brain injury

Submission date	Recruitment status
19/01/2008	No longer recruiting
Registration date	**Overall study status**
14/02/2008	Completed
Last Edited	**Condition category**
30/10/2008	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
This study was designed to evaluate whether sonographic measurements of the optic nerve diameter correlate with synchronous, non-invasive and invasive measurements of the intracranial pressure in brain-injured adults.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethics Committee of the General State Hospital of Athens, approved in 1999 (ref: 1999/02/ICUGG)

Study design
Prospective, randomised controlled study.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Severe brain injury

Interventions
All patients underwent non-invasive measurements of the intracranial pressure by transcranial Doppler sonography, and synchronous optic nerve diameter measurements by optic nerve sonography. Invasive measurements of the intracranial pressure by an intraparenchymal catheter were performed in 32 of the patients with severe brain injury.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

The following were measured within the first 24 h of admission to the intensive care unit:
1. Optic nerve diameter
2. Intracranial pressure
3. Neuroimaging results

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/10/2006

Completion date
31/08/2007

Eligibility

Key inclusion criteria
Intensive care patients who were hospitalized from October 2006 to August 2007

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
89

Key exclusion criteria
Patients with orbitofacial trauma or known disease of the optic nerve

Date of first enrolment
01/10/2006

Date of final enrolment
31/08/2007

Locations

Countries of recruitment
Greece

Study participating centre
Intensive Care Unit
Athens

Greece
11527

Sponsor information

Organisation
General State Hospital of Athens (Greece)

Sponsor details
Intensive Care Unit
154 Mesogeion Avenue
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soldatos@gmail.com

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00zq17821

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
General State Hospital of Athens, Intensive Care Unit (Greece)

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	01/10/2008		Yes	No