

Transcranial doppler sonography with a transorbital approach as a confirmatory test in the diagnosis of brain death

Submission date 26/09/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/10/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/10/2008	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 the routine addition of the transorbital doppler examination of the carotid siphon in patients suspected of brain death improves the efficiency of the transcranial doppler examination protocol.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study was approved by the Institutional Ethics Committee of the General State Hospital of Athens in 2005 (ref: ICUTCD2005/2).

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied

Brain death

Interventions

All patients underwent cerebral angiography, transcranial doppler examination of the basilar, anterior and middle cerebral arteries bilaterally. In addition, the patients in the intervention group were assessed by transorbital doppler of the carotid siphons bilaterally.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Blood flow patterns measured by transcranial doppler sonography with a suboccipital, transtemporal and transorbital approach.

Secondary outcome measures

Efficacy of the transorbital approach in the diagnosis of brain death with transcranial doppler sonography.

Overall study start date

01/10/2005

Completion date

31/07/2008

Eligibility

Key inclusion criteria

Brain dead patients of the intensive care unit (both males and females, aged greater than 16 years) who were hospitalised from October 2005 to July 2008.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

79

Key exclusion criteria

1. Patients with an episode of hypoxia or hypotension during the angiographic or transcranial doppler examinations
2. Patients with no flow at the initial transcranial doppler examination in any approach

Date of first enrolment

01/10/2005

Date of final enrolment

31/07/2008

Locations

Countries of recruitment

Greece

Study participating centre
154 Mesogeion Ave
Athens
Greece
11527

Sponsor information

Organisation
Athens General Hospital "G. Gennimatas" (Greece)

Sponsor details
ICU Department
154 Mesogeion Ave
Athens
Greece
11527
theosol@hotmail.com

Sponsor type
Hospital/treatment centre

Website
<http://www.gna-gennimatas.gr>

ROR
<https://ror.org/00zq17821>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Athens General Hospital "G. Gennimatas" (Greece) - Intensive Care Unit (ICU) Department

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