ISRCTN61258470 https://doi.org/10.1186/ISRCTN61258470

Ultrasound Cannulation of the Internal Jugular Vein

Submission date 10/04/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/05/2006	**Overall study status** Completed	
Last Edited 21/04/2011	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Ultrasound/022006

Study information

Scientific Title
Ultrasound Cannulation of the Internal Jugular Vein: a prospective randomised controlled study

Study objectives
This study was designed to evaluate whether real-time ultrasound-guided cannulation of the internal jugular vein is superior to the standard landmark method.

As of 08/11/2010 this record was updated to include an addition to the inclusion criteria as a result of a protocol change in January 2006. This is as follows:
"Ultrasound guided cannulation of the internal jugular vein versus the landmark method was extended at the subclavian vein site as from 2006 until 2010 in the same critical care population following the same methodology and the same protocol. Currently, 200 additional patients were enlisted for the ultrasound group and 201 additional patients were enlisted for the landmark group concerning the cannulation of the subclavian vein."

Thus, the inclusion criteria have been updated, and the target number of participants has been increased from 900 to 1301.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was in conformation with the principles outlined in the Declaration of Helsinki and was approved by the Institutional Ethics Committee 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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Critically ill patients

Interventions
Ultrasound-guided cannulation of the internal jugular vein versus the standard landmark method

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Cannulation of the internal jugular vein was achieved in all patients using ultrasound and in 425 of the patients (94.4%), the landmark technique (p <0.001) was used. Average access time (skin to vein) and the number of attempts were significantly reduced in the ultrasound group of patients compared to the landmark group (p<0.001). In the landmark group, puncture of the carotid artery occurred in 10.6% of patients, hematoma in 8.4%, hemothorax in 1.7%, pneumothorax in 2.4% and central venous catheter-associated blood stream infections in 16% which were all significantly increased compared to the ultrasound group (p<0.001).

Secondary outcome measures
There were no significant differences in gender, age, body mass index, left or right side of cannulation and in the presence of risk factors for difficult venous cannulation such as prior catheterization, limited sites for access attempts, previous difficulties during catheterization, previous mechanical complication, known vascular abnormality, untreated coagulopathy, skeletal deformity and cannulation during cardiac arrest between the two groups of patients. Furthermore, the physicians who performed the procedures had comparable experience in the placement of central venous catheters (p = non-significant).

Overall study start date
01/01/2000

Completion date
01/12/2006

Eligibility

Key inclusion criteria
Amended as of 08/11/2010:
Critical care patients which are hospitalised in the intensive care unit from January 2000 to December 2006 and were all mechanically ventilated requiring central/subclavian venous access for various therapeutic reasons.

Initial information at time of registration:
Critical care patients which are hospitalised in the intensive care unit from January 2000 to December 2006 and were all mechanically ventilated requiring central venous access for various therapeutic reasons.

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
1301 (added as of 08/11/2010; previously was 900)

Key exclusion criteria
Patients who were not on mechanical ventilation

Date of first enrolment
01/01/2000

Date of final enrolment
01/12/2006

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
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00zq17821

Funder(s)

Funder type
Hospital/treatment centre

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

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	01/08/2006		Yes	No
Results article	results	01/07/2011		Yes	No