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Comparison of TRIgemus-evoked SomatosEnsory Potentials and medianus-evoked somatosensory potentials in patients undergoing carotid surgery

Submission date 31/08/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/09/2006	**Overall study status** Completed	
Last Edited 04/07/2011	**Condition category** Surgery	

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
NCT00484796

Secondary identifying numbers
EK-BR-22/06-1

Study information

Scientific Title

Acronym
TRI-SEP-Study

Study objectives
Trigemus-evoked Somatosensory Potentials (TRI-SEP) may be used as an alternative to Medianus-evoked Somatosensory Potentials (MED-SEP) for the detection of cerebral ischaemic events during elective carotid surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval by the Ethics Committee of the Saxonian Chamber of Physicians (Ref-Nr: EK-BR-22/0-1).

Study design
Prospective, open, clinical study.

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Detection of cerebral ischaemic events during elective carotid surgery

Interventions
This study will compare the validity of both methods to detect cerebral ischaemic events, therefore in all patients Medianus- (MED-SEP) and Trigeminus- (TRI-SEP) evoked somatosensory potentials were taken during elective carotid surgery. The cognitive tests were taken in all

patients preoperatively and in the early postoperative course to document the cognitive function and detect cognitive disorders.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Cerebral ischaemic events during elective carotid surgery

Secondary outcome measures
Results of cognitive tests

Overall study start date
15/09/2006

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Agreemant with study procedures and informed consent
3. Elective carotid surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Inability to take somatosensory potentials
2. Inability to respond to the cognitive tests

Date of first enrolment
15/09/2006

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Germany

Study participating centre
Klinikum St. Georg gGmbH
Leipzig
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Sponsor information

Organisation
Klinikum St. Georg gGmbH (Germany)

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Sponsor type
Hospital/treatment centre

Website
http://www.sanktgeorg.de

ROR
https://ror.org/02y8hn179

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
This study is funded by our institution: Clinics of Anesthesiology, Critical Care and Pain Therapy

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	01/05/2011		Yes	No