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

Submission date	Recruitment status	Prospectively registered		
31/08/2006 Registration date	No longer recruiting Overall study status	☐ Protocol		
		Statistical analysis plan		
21/09/2006	Completed Condition category	[X] Results		
Last Edited		[] Individual participant data		
04/07/2011	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 Germany 04105

Sponsor information

Organisation

Klinikum St. Georg gGmbH (Germany)

Sponsor details

Clinic of Anaesthesia Critical Care and Pain Therapy Delitzscher Str. 141 Haus 20 Leipzig Germany 04105 +49 (0)341 909 2570 kais@sanktgeorg.de

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