

# Comparison of TRl gemus-evoked SomatosEnsory Potentials and medianus-evoked somatosensory potentials in patients undergoing carotid surgery

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|--|---|--|
| <b>Submission date</b><br>31/08/2006   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered    |
|  |   | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>21/09/2006 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b><br>04/07/2011       | <b>Condition category</b><br>Surgery              | <input type="checkbox"/> Individual participant data |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**ClinicalTrials.gov (NCT)**  
NCT00484796

**Protocol serial number**

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).

**Primary study design**

Interventional

**Study design**

Prospective, open, clinical study.

**Study type(s)**

Screening

**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 Trigemus- (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(s)**

Cerebral ischaemic events during elective carotid surgery

**Key secondary outcome(s)**

Results of cognitive tests

**Completion date**

31/12/2007

**Eligibility****Key inclusion criteria**

1. Aged over 18 years
2. Agreement with study procedures and informed consent
3. Elective carotid surgery

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**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

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# Sponsor information

## Organisation

Klinikum St. Georg gGmbH (Germany)

## 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

## 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/05/2011   |            | Yes            | No              |