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# The effects of selective neurogenic blockades on the perioperative immune reaction of patients undergoing lung resection (Pilotstudie zum einfluss selektiver neurogener blockaden auf die perioperative immunreaktion bei lungen-resezierten patienten)

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 21/03/2007 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 02/08/2007 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 01/09/2021 | 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

### Secondary identifying numbers
9991

# Study information

### Scientific Title
The effects of selective neurogenic blockades on the perioperative immune reaction of patients undergoing lung resection (Pilotstudie zum einfluss selektiver neurogener blockaden auf die perioperative immunreaktion bei lungen-resezierten patienten)

### Acronym
THORAX

### Study objectives
The overall interest of this study is to clarify if perioperative neurogenic blockades such as:
1. Thoracic epidural block (epidural ropivacain),
2. Central sympathetic inhibition via alpha-2 receptor stimulation (intravenous [i.v.] clonidine), or
3. Inhibition of the excitatory nonadrenergic-noncholinergic neurotransmission and of the hypothalamic-pituitary-adrenal axis (i.v. remifentanil),
can, by reducing the pro-inflammatory reactions immediately after surgery, effectively stop excessive anti-inflammation and consequently avoid immunosuppression after thoracic surgery. In this way selective neurogenic blockades could, as a perioperative preventive measure, contribute to lower the postoperative infection rate.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
The ethics committee were informed throughout and they gave permission for the performance of this clinical trial on the 27th December 2005 (ref: Ethics code LaGeSo Berlin/Germany 2005/12/27: EA 1/175/05).

### Study design
Monocentric, placebo controlled, double blind, randomised 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
Lung resection

### Interventions
There are three treatment arms:
1. Ropivacain
2. Remifentanil
3. Remifentanil plus Clonidin

These will be given as follows:
1. After epidural placement of the catheter 10 ml bolus ropivacain 0.75%/placebo epidural
2. After anaesthesia induction 150 µg bolus clonidin/placebo intravenous
3. Epidural syringe pump with ropivacain 0.2%/placebo 6 - 10 ml/h during surgery
4. Intravenous syringe-pump with clonidin/placebo 20 - 100 µg/h during surgery
5. Intravenous syringe-pump with remifentalil 0.2%/placebo 0.2 - 0.4 µg/kg/min during surgery

The interventional treatment is limited to the duration of surgery and therefore depends on operation time; we perform neither pre- nor post-operative interventions. The follow up period amounts to three postoperative days.

### Intervention Type
Drug

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
Remifentanil, clonidine and ropivacain

### Primary outcome measure
T1/T2 ratio, measured immediately after surgery and in the first, second and third postoperative at rounds time in the morning.

### Secondary outcome measures
Postoperative infections, measured immediately after surgery and in the first, second and third postoperative at rounds time in the morning.

### Overall study start date
01/01/2006

### Completion date
01/07/2007

## Eligibility

### Key inclusion criteria
Lung resection

### Participant type(s)
Patient

### Age group
Not Specified

### Sex
Not Specified

### Target number of participants
60

### Total final enrolment
60

### Key exclusion criteria
1. Patient under age
2. Pregnancy
3. Contraindications for epidural block
4. Contraindications for ropivacain
5. Contraindications for remifantanil
6. Contraindications for clonidine
9. Treatment with local anaesthetics
10. Treatment with central anti-adrenergic drugs (clonidine, methyldopa, moxonidine, reserpine)
11. Treatment with opioids
12. Myocardial Infarction (MI) within the last eight weeks
13. Cardiac insufficiency New York Heart Association (NYHA) III and IV

### Date of first enrolment
01/01/2006

### Date of final enrolment
01/07/2007

## Locations

### Countries of recruitment
Germany

### Study participating centre
**Charité - Universitätsmedizin Berlin**
Berlin
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## Sponsor information

### Organisation
Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany)

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### Sponsor type
Hospital/treatment centre

### Website
http://www.charite.de/ch/anaest/

### ROR
https://ror.org/001w7jn25

## Funder(s)

### Funder type
Other

### Funder Name
This is an investigator initiated and funded trial (Germany)

## 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 | | 01/02/2012 | 01/09/2021 | Yes | No |