

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 21/03/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 02/08/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 01/09/2021	Condition category Surgery	☐ 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

Protocol serial number
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).

Primary study design

Interventional

Study design

Monocentric, placebo controlled, double blind, randomised study

Study type(s)

Treatment

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 remifentanyl 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)

Remifentanyl, clonidine and ropivacain

Primary outcome(s)

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

Key secondary outcome(s)

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

Completion date

01/07/2007

Eligibility**Key inclusion criteria**

Lung resection

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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 remifentanyl
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

Germany

D-10117

Sponsor information

Organisation

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

ROR

<https://ror.org/001w7jn25>

Funder(s)

Funder type

Other

Funder Name

This is an investigator initiated and funded trial (Germany)

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?
Results article		01/02/2012	01/09/2021	Yes	No