

# Influence of pre-operative vaccination on immune response and post-operative infection rate

<b>Submission date</b> 11/08/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/01/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/05/2016	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Claudia Spies

**Contact details**  
Department of Anaesthesiology and Intensive Care Medicine  
Charite Universitaetsmedizin Berlin  
Augustenburgerplatz 1  
Berlin  
Germany  
13353  
+49 (030) 450 551001  
anaesth@charite.de

## Additional identifiers

**EudraCT/CTIS number**  
2004-004352-40

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

N/A

# Study information

## Scientific Title

Influence of pre-operative vaccination on immune response and post-operative infection rate

## Study objectives

Pre-operative vaccination with influenza antigen improves post-operative immune suppression.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics board committee Berlin, Landesamt für Gesundheit und Soziales (LaGeSo), Berlin, 11/03/2005, ref: EA 1/048/04

## Study design

Prospective randomised double-blind placebo-controlled clinical trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Upper aerodigestive tract cancer undergoing surgery

## Interventions

Vaccination with influenza haemagglutinin antigen versus a placebo control group.

## Intervention Type

Biological/Vaccine

## Primary outcome measure

Influence of pre-operative vaccination on immune response.

## Secondary outcome measures

Influence of pre-operative vaccination post-operative infection rate.

**Overall study start date**

01/11/2005

**Completion date**

01/01/2009

## **Eligibility**

**Key inclusion criteria**

Tumour resection of upper aerodigestive tract.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

40 (75 as of 30/03/2009)

**Key exclusion criteria**

Initial information at time of registration:

1. No consent
2. Under 18 years
3. Liver insufficiency (more than Child B)
4. Acute Coronary Syndrome (less than 8 weeks)
5. Human Immunodeficiency Virus (HIV) positive
6. Corticosteroidal treatment
7. After organ transplantation
8. Current infection
9. Pregnancy

Added as of 30/03/2009:

10. Diabetes mellitus
11. Status post splenectomy
12. Protein deficiency
13. Known allergy to components of the vaccine
14. Immunosuppression

**Date of first enrolment**

01/11/2005

**Date of final enrolment**

01/01/2009

# Locations

## Countries of recruitment

Germany

## Study participating centre

Charite Universitaetsmedizin Berlin

Berlin

Germany

13353

# Sponsor information

## Organisation

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

## Sponsor details

c/o Prof. Claudia Spies

Department of Anaesthesiology and Intensive Care Medicine

Augustenburgerplatz 1

Berlin

Germany

13353

## Sponsor type

University/education

## Website

<http://www.charite.de/ch/anaest/>

## ROR

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

# Funder(s)

## Funder type

University/education

## Funder Name

Charité Universitätsmedizin Berlin

## Alternative Name(s)

Medical School - Charité - University Medicine Berlin

### **Funding Body Type**

Private sector organisation

### **Funding Body Subtype**

For-profit companies (industry)

### **Location**

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?
<a href="#">Results article</a>	results	01/08/2015		Yes	No