ISRCTN16108096 https://doi.org/10.1186/ISRCTN16108096

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

Submission date 11/08/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/01/2007	**Overall study status** Completed	
Last Edited 16/05/2016	**Condition category** Cancer	

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. Corticosteriodal 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?
Results article	results	01/08/2015		Yes	No