

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

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

Clinical Trials Information System (CTIS)
2004-004352-40

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

Study type(s)

Treatment

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(s)

Influence of pre-operative vaccination on immune response.

Key secondary outcome(s)

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

Completion date

01/01/2009

Eligibility

Key inclusion criteria

Tumour resection of upper aerodigestive tract.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

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