Preventie van infecties na open chirurgische ingrepen

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25596

Source
NTR

Brief title
BeTRAINED

Health condition

Post-operative infection
Surgical site infection
Pneumonia
Sepsis

Sponsors and support

Primary sponsor: Radboud university medical center
Source(s) of monetary or material Support: Radboud university medical center

Intervention

Outcome measures

Primary outcome

Main study outcome is the assessment of immune cell function after BCG vaccination and after surgery

Secondary outcome

Secondary outcomes are the occurrence of SSI, pneumonia, sepsis, UTI, ileus

Study description

Background summary

Despite strictly implemented perioperative infection-preventive strategies, postoperative infection rates are still high (up to 20%). Surgery- and anesthesia induced immunosuppression contributes to such infections, which are associated with high mortality rates. In this project, this perioperative-induced immunosuppression will be investigated by a unique approach: We aim to improve patient's host defence mechanisms by vaccination with Bacillus Calmette–Guérin (BCG), in order to facilitate a more efficient elimination of pathogens during the perioperative period. The inflammatory response after elective laparotomic surgery in BCG-vaccinated patients will be compared with placebo–vaccinated patients in a double-blind randomized trial.

Study objective

We hypothesize that induction of trained immunity through BCG vaccination may improve host defence mechanisms of patients throughout the perioperative period.

Study design

- Immediately before the intervention

- Immediately pre-surgery (before induction of anesthesia)

- Immediately post-surgery (on the arrival at the recovery room)

- 30 days after surgery (between 28-32 days)

- 90 days after surgery (between 80-100 days)

Intervention

BCG vaccination

Contacts

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Eligibility criteria

Inclusion criteria

Willing and able to provide written informed consent.

No acute infection at the time of vaccination or surgery (defined as fever above 38.5 ¢XC).

Patients scheduled for:

Colon surgery, sigmoid surgery, or rectal surgery via an open laparotomy.

Liver and gall bladder surgery via an open laparotomy.

Pancreas surgery (Whipple procedures) via an open laparotomy.

Uterus/ovaria extirpations, tumour debulking surgery via an open laparotomy.

Nefrectomy/urinary bladder surgery via an open laparotomy.

Vascular surgery (aortic) via an open laparotomy.

Exclusion criteria

Immunosuppressed status, due to medication or otherwise.

Corticosteroid or other immunosuppressive treatment, including general radiation. Inhaled steroids are not a contra-indication.

Malignant condition such as lymphoma, leukaemia or other tumour of the reticulo-endothelial system that is not in remission.

HIV infection

Auto-inflammatory or auto-immune „ª diseases.

Pregnancy or lactation.

Any serious or active medical or psychiatric illness which would interfere with treatment, assessment, or compliance.

History of TBC infection or positive Mantoux test, contact with TBC patients or born in a TBC endemic country.

Vaccination within 3 months prior to inclusion (subjects cannot be vaccinated with other vaccines during the study).

Previous BCG vaccination or known allergy or hypersensitivity to BCG vaccine.

History of serious atherosclerotic disease (unstable Angina Pectoris, history of ischemic CVA).

History of diabetes mellitus type 2 with metformin as anti-diabetic medication.

Participation in a clinical study with an investigational drug or biologic within 28 days prior to screening visit.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-11-2018
Enrollment:	104
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7092
NTR-old	NTR7290
CCMO	NL66332.091.18

Study results