Preventie van infecties na open chirurgische ingrepen

Gepubliceerd: 19-06-2018 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25596

Bron
NTR

Verkorte titel
BeTRAINED

Aandoening

Post-operative infection
Surgical site infection
Pneumonia
Sepsis

Ondersteuning

Primaire sponsor: Radboud university medical center
Overige ondersteuning: Radboud university medical center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

- 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)

Onderzoeksproduct en/of interventie

BCG vaccination

Contactpersonen

Publiek

L.S. Helder
Geert Grooteplein Zuid 10

Nijmegen 6525 GA
The Netherlands
+31 24 3668289

Wetenschappelijk

L.S. Helder
Geert Grooteplein Zuid 10

Nijmegen 6525 GA
The Netherlands
+31 24 3668289

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-11-2018
Aantal proefpersonen:	104
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten