

IMMUNE RESPONSE INDUCED BY VACCINATION WITH BCG

Gepubliceerd: 29-10-2013 Laatste bijgewerkt: 18-08-2022

THE LACK OF PROTECTION BY BCG MAY BE THE CONSEQUENCE OF REGULATORY T CELL INDUCTION OR ACTIVATION. SECONDLY, RECOGNITION OF MYCOBACTERIAL ANTIGENS MAY BE DIFFERENT AFTER INFECTION AND VACCINATION.

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29225

Bron

NTR

Verkorte titel

BCG-VACCIN

Aandoening

local pain, irritation or discomfort at the injection site (immediately after the injection)=common

uncommon= headache, fever local; enlargement of regional lymph node >1cm. Ulceration with a severe discharging ulcer at the site of injection.

Rare: disseminated BCG complications such as osteitis or osteomyelitis, allergic reactions, including anaphylactic reactions. Local suppurative lymphadenitis, abscess formation.

Ondersteuning

Primaire sponsor: Performer; University Medical Center

Overige ondersteuning: initiator sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

to characterize the anti-mycobacterial immune responses during vaccination with live-attenuated M. bovis BCG Danish strain 1331, in order to provide a framework for using biomarkers in future TB vaccine trials.

Toelichting onderzoek

Achtergrond van het onderzoek

Tuberculosis is a growing global health problem. The only available vaccine is Bacille Calmette-Querin (BCG). It protects young children from severe forms of tuberculosis, but it is of limited value in adults. We hypothesize that the antigen expression profile of BCG during intradermal vaccination is different from that of Mycobacterium tuberculosis. The partial failure of BCG may be related to this difference.

Doel van het onderzoek

THE LACK OF PROTECTION BY BCG MAY BE THE CONSEQUENCE OF REGULATORY T CELL INDUCTION OR ACTIVATION. SECONDLY, RECOGNITION OF MYCOBACTERIAL ANTIGENS MAY BE DIFFERENT AFTER INFECTION AND VACCINATION.

Onderzoeksopzet

heparine blood, (paxgene, serum): -2 week, 0, +1 day, +3 day, +7 day, 4, 8, 12, 52 weeks

Urine sample: -2 week, +1, +3, +7, 8 weeks

QFN; -2 weeks

Onderzoeksproduct en/of interventie

BCG VACCINE SSI (DANISH STRAIN 1331; RVG NUMBER 17661)

Contactpersonen

Publiek

[default]

The Netherlands

Wetenschappelijk

[default]

The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

HEALTHY

AGE 18-55 YEAR

SIGNED WRITTEN INFORMED CONSENT

NAIVE FOR TUBERCULOSE (NEGATIVE TST AND NEGATIVE QFN)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

HISTORY OF TB DISEASE OR TREATMENT

BCG VACCINATION

LIVE VACCINATION

TREATMENT WITH IMMUNE MODULATING DRUGS

(HISTORY OF) DISEASE AFFECTING THE LYMPHOID ORGANS

KNOWN CONGENITAL OR ACQUIRED IMMUNE DEFICIENCIES

POSITIVE HIV TEST

FEVER OR ANTIBIOTIC TREATMENT 2 WEEKS OR LESS PRIOR TO ENROLMENT

KNOWNHYPERSENSITIVITY TO ANY OF THE VACCINE COMPONENTS

POSITIVE PREGNANCY TEST AT SCREENING

FEMALES NOT WILLING TO USE CONTRACEPTIVES DURING THE FIRST 8 WEEKS FOLLOWING VACCINATION, OR IF BREASTFEEDING

ACTIVE PARTICIPATION IN OTHER CLINICAL TRIALS

DOES NOT CONSENT TO US INFORMING THE PARTICIPANT'S GENERAL PRACTITIONER OF THE BCG VACCINATION AND OF ANY UNCOMMON, RARE OR SERIOUS ADVERSE EVENTS

HAS A CONDITION WHICH IN THE OPINION OF THE INVESTIGATOR IS NOT SUITABLE FOR PARTICIPATION IN THE CLINICAL TRIAL

Onderzoeksopzet

Opzet

Type: Interventie onderzoek
Onderzoeksmodel: Anders
Toewijzing: N.v.t. / één studie arm

Controle: Geneesmiddel

Deelname

Nederland
Status: Anders
(Verwachte) startdatum: 01-10-2012
Aantal proefpersonen: 25
Type: Onbekend

Ethische beoordeling

Positief advies
Datum: 29-10-2013
Soort: Eerste indiening

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	NL4101
NTR-old	NTR4245
Ander register	: BCG-study
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A