Detecting the antigen-specific B-cell-response to rabies vaccination.

Gepubliceerd: 20-02-2020 Laatst bijgewerkt: 18-08-2022

We hypothesize that we are able to develop a flow-cytometric assay that is able to detect rabies-specific B-cells in the blood of hyperimmunized people.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24167

Bron
Nationaal Trial Register

Verkorte titel
ASPERA

Aandoening

Rabies

Ondersteuning

Primaire sponsor: LUMC
Overige ondersteuning: LUMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

An optimal combination of concentrations of rabies virus and rabies-specific antibodies will be used to detect and quantify the population of rabies-specific B-cells using flow cytometry. We expect to see no rabies-positive B-cell events in unvaccinated individuals. If we see a rabies-

positive B-cell population in hyperimmunized individuals, we can conclude that our assay is able to detect rabies-specific B-cells, which is our primary endpoint.
This outcome will be measured in blood drawn from the participants via venipuncture at one single timepoint. This timepoint is independent of the most recent rabies vaccination.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Rabies is a fatal disease, for which adequate pre- and post-exposure prophylaxis is available in the form of vaccination with inactivated virus. Serological testing (measuring titers of rabies-specific antibodies) is the conventional way to determine if someone is protected from rabies. Although cellular parameters might also contain valuable information in the prediction of protection against rabies, such parameters have never been studied in great detail.
The development of an assay which allows detection and quantification of antigen-specific immune cells and the description of their kinetics over time may open up many new possibilities, such as improved assessment of vaccine efficacy. Additionally, as rabies virus is a so-called neo-antigen, the magnitude and diversity of cellular responses to the vaccine can be used in the diagnosis and follow-up of patients with immune system disorders, particularly in case of suspected B-cell defects.
To develop such an antigen-specific assay, we need to have access to peripheral blood samples obtained from individuals with a relatively high frequency of rabies-specific immune cells, such as hyperimmunized volunteers who have received multiple consecutive rabies vaccinations.
Objective: This study is designed to develop a flow-cytometric assay that can detect rabies-specific B-cells generated in response to vaccination.
Study design: This is a cross-sectional study in which 10 hyperimmunized participants will be asked to donate a single sample of 53.5 ml blood (50 ml in EDTA tubes and 3.5 ml in a serum tube) and to complete a short questionnaire on their rabies vaccination history. The blood samples will be processed to isolate peripheral blood mononuclear cells which will either be used fresh, or be frozen for later use.The samples will be used to test and optimize the assay for detection of rabies antigen-specific cells.
Study population: Up to 10 healthy adult volunteers who have received multiple rabies vaccinations due to profession-related activities, which include potential contact with live rabies virus or related viruses. The control population consists of up to 10 healthy adult volunteers who have not been vaccinated against rabies.
Main study parameters/endpoints: Detection and quantification of rabies-specific B-cells.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The burden of the study is limited and related to a single donation of blood. Risks include local reactions to drawing of blood, such as local hematoma or pain.

Doel van het onderzoek

We hypothesize that we are able to develop a flow-cytometric assay that is able to detect rabies-specific B-cells in the blood of hyperimmunized people.

Onderzoeksopzet

Day 0. One single timepoint at one single visit, which is independent of the most recent rabies vaccination or the lack thereof.

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a hyperimmunized subject must meet all of the following criteria:
- 18 years old or older.
- Received at least 3 rabies vaccinations.
- Able to provide informed consent.

A control subject must meet the following criteria:

- 18 years old or older.
- Never received rabies vaccinations.
- Able to provide informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- History of (pre)syncope associated with medical procedures involving needles.
- Received any vaccination other than rabies three months prior to inclusion.
- Administration of plasma or blood products three months prior to inclusion.
- Bleeding disorders or use of anticoagulants.
- Any current infectious disease other than seasonal cold.
- Immunocompromised (due to medication, medical condition, or other).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2020
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	20-02-2020
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	NL8404
Ander register	METC-LDD : P20.004

Resultaten