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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24167

Source
NTR

Brief title
ASPERA

Health condition

Rabies

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: LUMC

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

In an explorative setting, we want to see if we can quantify the population of rabies-specific B-cells in different donors, using flow cytometry. Furthermore, we would like to explore if we can further classify the rabies-specific population into different B-cell subsets.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.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2020
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	20-02-2020
Application type:	First submission

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	NL8404
Other	METC-LDD : P20.004

Study results