How well does the immune system remember rabies immunization after one or two injections?

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24881

Source Nationaal Trial Register

Brief title PREPARE

Health condition

Rabies, lyssavirus, rabiës, hondsdolheid

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC), Department of Infectious Diseases **Source(s) of monetary or material Support:** ZonMW

Intervention

Outcome measures

Primary outcome

Rate of increase of GMC of RVNA between day 0 and day 7 after simulated PEP.

Secondary outcome

Percentage of travellers with RVNA titer >0.5 IU/mL at day 0, two months, and six months after primary vaccination. Percentage of travellers with RVNA titers>0.5 IU/mL at day 3, after the simulated post-exposure vaccination. Percentage of travellers with RVNA titers>3 IU/mL, and percentage of travellers with RVNA titers >5 IU/mL at day 7 after simulated PEP.

GMC of RVNA at 0, 2, and 6 months after a single intramuscular dose of rabies vaccine GMC of RVNA at 0, 2, and 6 months after a two-site intradermal one-fifth fractional doses of rabies vaccine GMC of RVNA at 0, 2, and 6 months after standard PrEP with 2 intramuscular doses of rabies vaccine GMC of RVNA at day 0, day 3, day 7 and day 21 after the simulated post-exposure vaccination

Knowledge, belief and risk perception about animal bites and rabies vaccination, before and after travel

Percentage of travellers with animal contact during stay abroad

Type of animal and type of contact (licking, scratching or biting)

Measures taken after animal contact during travel Percentage of travellers who applied wound care after animal contact

Percentage of travellers who started appropriate PEP after animal contact

Study description

Background summary

The main purpose of prophylactic rabies pre-exposure immunization (PrEP) is to induce an effective and rapid anamnestic antibody response after revaccination that obviates the need for human rabies immunoglobulins (RIG) and simplifies post-exposure immunization (PEP) to

2 - How well does the immune system remember rabies immunization after one or two in ... 13-05-2025

just 2 doses of rabies vaccine (D0, D3).

Many travellers decline pre-travel PrEP because of costs and insufficient time between visit at the travel clinic and departure.

The aim of this study is to demonstrate that a single dose of rabies vaccine can induce an equally rapid and adequate anamnestic antibody response as 2-dose PrEP to revaccination six months later.

Travellers will be randomized between 2-dose PrEP, single dose PrEP (standard intramuscular dose or one-fifth fractional intradermal dose) and no PrEP before travel. After 6 months, all subjects receive a simulated 2-dose post-exposure vaccination schedule (D0 and D3).

Serum samples are collected at 0, 2, and 6 months after PrEP, and at 0, 3, 7 and 21 days after the simulated post-exposure vaccinations.

The primary endpoint is the rate of increase of geometric mean concentrations (GMC) of neutralizing antibodies between day 0 and day 7 after revaccination for the different study groups.

If PrEP with a single dose of rabies vaccine would be equally effective in inducing a rapid and adequate anamnestic antibody response, RIG would not be no longer required in case of high risk bite wounds in (returning) travellers. Guidelines on pre-travel PrEP could be simplified. Pre-travel rabies PrEP would come within reach of most travellers.

Study objective

The aim of this study is to demonstrate that a single dose of rabies vaccine can induce an equally rapid and adequate anamnestic antibody response as 2-dose PrEP to revaccination six months later.

Study design

Primare outcome: D0 and 7 after simulated PEP (month 6 + 0 days and month 6 + 7 days)

Intervention

Two intervention groups:

- Study group A – single standard dose of 1.0 mL rabies vaccine on D0

- Study group B – two fractional doses of 0.1 mL rabies vaccine by intradermal route at different sites on D0 $\,$

3 - How well does the immune system remember rabies immunization after one or two in ... 13-05-2025

Two control groups:

- Study group C (positive control) – wo-dose (1.0 mL) intramuscular PrEP vaccination (D0, D7)

- Study group D (negative control) – no rabies vaccination before travel

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

Travellers visiting the travel clinics of AMC, LUMC and the 'Tropen Advies Centrum – Travel Clinic

Havenziekenhuis' will be invited to participate in this study. In order to be eligible to participate in this study, a subject must meet all of the following criteria:

Age ≥18 years

- Expected time of departure >1 week
- Travelling for less than 8 weeks
- · Good health according to investigator
- Willingness and ability to adhere to the study regimen
- 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 previous rabies vaccination
- Requirement for standard rabies PrEP according to the national guidelines

- Suspected previous vaccination against rabies
- Known or suspected severe allergy against egg protein
- Known or suspected allergy against any of the other vaccine components
- History of unusual or severe reactions to any previous vaccination
- History of (pre)syncope associated with medical procedures involving needles
- Immunocompromized state due to illness or medication
- Administration of plasma or blood products three months prior to inclusion
- (hydroxy)chloroquine or mefloquine use
- History of any neurological disorder including epilepsy
- Pregnancy or breastfeeding
- Any current infectious disease other than seasonal cold
- Bleeding disorders or use of anticoagulants

• Temporary exclusion criterion for vaccination: body temperature \geq 38.5°C or acute illness will lead to postponement of participation and vaccination. Screening may continue when the temperature has normalized.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL Recruitment status:

Recruiting

5 - How well does the immune system remember rabies immunization after one or two in ... 13-05-2025

Start date (anticipated):	17-05-2018
Enrollment:	246
Туре:	Anticipated

Ethics review

Positive opinion	
Date:	09-11-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45358 Bron: ToetsingOnline Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6600
NTR-old	NTR6817
ССМО	NL60550.056.17
OMON	NL-OMON45358

Study results