Hoe goed herinnert het afweersysteem een inenting tegen hondsdolheid vijf jaar na een enkele injectie?

Gepubliceerd: 25-10-2021 Laatst bijgewerkt: 15-05-2024

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 3-dose PrEP to revaccination five years later.

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Virale infectieziekten
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22516

Bron
Nationaal Trial Register

Verkorte titel
SIRAVA

Aandoening

- Virale infectieziekten

Aandoening

Rabies

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor:	Leiden University Medical Center (LUMC), Department of Infectious Diseases

Secundaire sponsoren:	Bavarian Nordic
Overige ondersteuning:	Bavarian Nordic A/S

Onderzoeksproduct en/of interventie

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

Rate of increase of GMC of RVNA between day 1 and day 8 after simulated PEP.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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 just 2 doses of rabies vaccine (D1, D4) in case of high-risk bite wounds. Many travellers decline pre-travel PrEP because of costs and insufficient time between visit at the travel clinic and departure. If a single dose of rabies vaccine would be equally effective in inducing a rapid and adequate anamnestic antibody response, guidelines on pre-travel PrEP could be simplified. In particular, the induction of long-term immunological memory might be an issue in the case of single-visit PrEP. To evaluate if single-visit PrEP is a reasonable alternative for one of the approved current standards, three-visit PrEP, we aim to study whether single-visit priming results in non-inferior long-term immunological memory, that is boostable by simulated post-exposure prophylaxis (PEP) after five years. 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 3-dose PrEP to revaccination five years later. Study design: Randomized controlled non-inferiority trial. Study population: Healthy adult volunteers. Intervention: Participants will be randomized between standard 3-dose intramuscular PrEP (D1, D8, D22) or single-dose PrEP (standard intramuscular dose). After 5 years, all subjects will receive a simulated 2-dose post-exposure intramuscular vaccination schedule (D1 and D4). Serum (all participants) and blood samples (50 participants) are collected after PrEP at D1, D57/D78 (depending on study group), year 1, year 2 and year 5; and at D1, D8 and D15 after simulated PEP vaccination. Main study parameters/endpoints: The primary endpoint is the rate of increase of geometric mean concentrations (GMC) of neutralizing antibodies between day 1 and day 8 after revaccination. Nature and extent of the burden and risks associated with participation, benefit and group relatedness: In total, 3 or 5 injections will be given with a registered rabies vaccine. A maximum of 98 mL of blood will be collected during 7 sampling moments. Depending on the study arm eight to ten visits

are required for the study. Participants are asked to complete a diary for safety evaluation during the study. The standard 3-dose PrEP (D1, D8, D22) has been endorsed by the WHO. No risks are associated with participation in this study other than those of routine vaccination and minimal to moderate physical discomfort that can be experienced after vaccination or the collection of blood. Participants will receive financial compensation for their participation.

Doel van het onderzoek

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 3-dose PrEP to revaccination five years later.

Onderzoeksopzet

D1 (baseline), D57 or D78, Y1, Y2, and Y5 D1 (day of first dose of simulated rabies PEP), Y5 D8 and Y5 D15.

Onderzoeksproduct en/of interventie

- Study group A – one single intramuscular dose (1 mL) of rabies vaccine (D1) - Study group B – standard three-dose (1 mL) intramuscular PrEP vaccination (D1, D8, D22)

Contactpersonen

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Netherlands

Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Age ≥18 years • Good health according to investigator • Willingness and ability to adhere to the study regimen • Able to provide informed consent • Naïve to rabies exposure or vaccination • Willing to comply to a follow-up of 5 years • Unlikely to require rabies PrEP in next 5 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• History of previous rabies vaccination • 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

Onderzoeksopzet

Opzet

Fase onderzoek:	4
Type:	Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel
Doel:	Preventie

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	10-01-2022
Aantal proefpersonen:	200
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Goedgekeurd WMO

Datum:	28-12-2021
Soort:	Eerste indiening
Toetsingscommissie:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 51662
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9827
CCMO	NL79547.058.21
OMON	NL-OMON51662

Resultaten