Dutch Marines study on Rabies antibody response after Boostering an intradermal pre-exposure scheme (MaRaBoo study)

Published: 11-11-2016
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To gain insight in speed of onset and levels of antibody titers ("boostability") after a completed intradermal pre-exposure rabies immunization.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON45312

Source
ToetsingOnline

Brief title
MaRaBoo study

Condition

- Viral infectious disorders

Synonym
Rabies

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van Defensie

Intervention

Keyword: Immunization, Rabies, Vaccination

Outcome measures

Primary outcome

The percentage of participants with a titer of * 0.5 IU/ml at day 7

The percentage of participants with a titer of * 0.5 IU/ml at day 14

Secondary outcome

The percentage of participants with a titer of * 0.5 IU/ml at day 0

The percentage of participants with a titer of * 3.0 IU/ml at day 7

The percentage of participants with a titer of * 3.0 IU/ml at day 14

Study description

Background summary

Rabies is a neglected disease with a case-fatality rate of almost 100% in humans who develop symptoms. Human rabies causes more than 55.000 deaths annually worldwide. In 99% of human rabies, transmission is due to the bite of a rabies-infected dog. Rabies is fully preventable by prompt wound care, and the availability of vaccines and human anti-rabies immunoglobulin (HRIG). In the past 10 years, three fatal cases of rabies occurred in The Netherlands, all in the AMC. The disease can be prevented by pre-exposure prophylaxis (PrEP). This prophylaxis, consisting of three immunizations on Days 0, 7 and 21-28, is highly recommended for those at risk, like military personnel.
Little is known about the quantitative immune response directly after post-exposure immunization. This immune response to PEP is referred to as *boostability* in literature.
Although studies show positive results on boostability on Days 14 and 28 after booster immunization, data on antibody response directly after booster immunization are scarce.
In this study, we are primarily interested in the rabies antibody concentration during the first weeks after intradermal immunization, reflecting the immunological memory.
The study set out to explore the hypothesis that a rapid antibody response is initiated after booster immunization, resulting in protective antibody levels

within a week.

Study objective

To gain insight in speed of onset and levels of antibody titers ("boostability") after a completed intradermal pre-exposure rabies immunization.

Study design

Observational cohort study

Study burden and risks

There are no direct benefits for the military personnel. The risk for the military personnel is minimal, the only interventions are three vena punctures.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy military volunteers that received a completed intradermal immunization last year or 2 years ago.

Exclusion criteria

- Age < 18 years;
- No previous booster immunization;
- No previous post-exposition treatment with HRIG;
- Potential deployment to rabies endemic area within study period ;
- Presence of a serious medical history with a potential effect on the immune system such as diabetes mellitus, HIV, functional or hyposplenia/asplenia;
- Allergies to one of the components of the rabies vaccine such as chicken egg protein, polygeline, hypersensitivity to neomycin, chlortetracycline, amphotericin B and other antibiotics of the same class;
- Use of mefloquine or chloroquine during the study period ;
- Pregnancy ;
- Breastfeeding;
- Immune compromised due to medication such as prednisolone, TNF-alfa inhibitors, *biologicals* or immunodeficiency due to humoral or cellular cause.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-11-2016

Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	11-11-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL59466.018.16

Study results

Date completed:	04-02-2019
Actual enrolment:	24

Summary results

Trial ended prematurely