# Rabiës pre exposure prophylaxis in patients with auto-immune diseases using immunosuppressive agents.

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|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON25639

**Bron**
NTR

**Verkorte titel**
VIPRAR

**Aandoening**

Auto-immune diseases (Inflammatory bowel disease/rheumatoid arthritis)

### Ondersteuning

**Primaire sponsor:** The International Society of Travel Medicine (ISTM)
**Overige ondersteuning:** The International Society of Travel Medicine (ISTM)

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Boostability, defined as the proportion of patients who received a 3-dose PrEP schedule (0,7,28) and had adequate antibody levels >0.5 IU/L at day 7 after the 2-dose PEP schedule (0,3) given 1 year after the PrEP schedule.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Rabies is a neglected disease with a case-fatality rate of almost 100% in humans who develop symptoms. In 99% of human rabies, transmission is due to the bite of a rabies-infected dog. Rabies is fully preventable through the administration of rabies vaccines and rabies immunoglobulins (RIG).
After a potential exposure to rabies in a healthy unvaccinated person, post exposure prophylaxis (PEP) treatment consists of four rabies immunizations and RIG. By contrast, healthy persons who previously received rabies pre-exposure prophylaxis (PrEP) can suffice with a shortened PEP schedule, consisting of only two vaccinations without RIG.
For ICPs however, there are insufficient data on immunogenicity and boostability of this PrEP schedule. The recommended PrEP schedule for ICPs currently consists of three doses of rabies vaccine (days 0, 7, 21-28). For ICPs, however, adequately administered PreP does not preclude the need for RIG after a potential rabies exposure. Therefore, rabies PrEP currently does not benefit ICP travelers as much as healthy travelers. The goal of this study is to investigate the immune response after 3 doses of rabies vaccine (PrEP; day 0,7,21-28) and boostability 1 year after PrEP by admnistering 2 doses rabies vaccine (PEP; year 1 and year 1+3 days) in patients with auto-immune diseases using TNF-alpha inhibitor or DMARD monotherapy. Antibody levels will be measured by The Rapid Focus Fluorescent Inhibition Test (RFFIT).
Antibody levels above 0.5IU/L will be considered as adequate according to WHO definitions.

### Doel van het onderzoek

Rabies vaccine is very immunogenic in healthy people. The WHO considers a post-vaccination antibody titer of at minimum 0.5 IU/ml as adequate cut-off for successful vaccination. Case reports show adequate rabies antibody responses (RAR) after vaccination in ICPs using immunosuppressive therapy.
We hypothesize that in patients with auto-inflammatory diseases treated with immunosuppressive monotherapy, the immunogenicity and boostability following a 3-dose PrEP schedule is sufficient to safely recommend a shortened PEP schedule without RIG, following potential rabies exposure.

### Onderzoeksopzet

Day 0, day 7, day 21-28, day 60, month 12, month 12+3 and month 12+ 7

**Onderzoeksproduct en/of interventie**

We offer all eligible ICPs a three-dose rabies PrEP schedule on days 0, 7 and 21-28 intramuscularly, according to the current WHO guidelines for ICPs.
At month 12, a 2-dose rabies PEP schedule will be administered intramuscularly at day 0 and day 3. Serum samples will be taken on day 0, day 28, day 60, month 12 and month 12+ 7 days to determine rabies antibody levels.
The Rapid Focus Fluorescent Inhibition Test (RFFIT) is considered the gold standard to determine rabies antibodies. All blood samples will be sent to an external rabies reference center for RFFIT. Antibody levels above 0.5IU/L will be considered as adequate according to WHO definitions.

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Adults aged 18-70 years old with a chronic inflammatory condition requiring treatment with one of the following drugs: adalimumab, infliximab, etanercept, golimumab, certolizumab, methotrexate, azathioprine, 6-mercaptopurine, thioguanine, steroids, tacrolimus or mycophenolic acid.
• Being naïve to rabies vaccines
• Anticipated travel to a rabies-endemic country in the future

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Diagnosis of one of the following
o Primary immune deficiency disorder
o Active malignancy
o Anyone who received chemotherapy or anti-CD20 in the past 2 years.
o Hemophilic disorder precluding intramuscular vaccination
o (Functional) asplenia
o Allergy to any of the components of the rabies vaccine.
• Pregnant
• Not able or willing to consent
• Using other immunosuppressive agents than the mentioned

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Niet-gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-06-2020 |
| Aantal proefpersonen: | 50 |
| 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: | 02-12-2020 |
| 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 | NL9087 |
| Ander register | METC AMC (Amsterdam UMC, Location AMC) : METC2018_108 |

# Resultaten