

Ticking on Pandora's Box

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We hypothesize that the other tick-borne pathogens are pathogenic and cause significant clinical disease in the Netherlands

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27838

Bron

NTR

Verkorte titel

Pandora

Aandoening

Lyme borreliosis, anaplasmosis, babesiosis, Borrelia miyamotoi disease, neorickettsiosis, rickettsiosis, tick-borne encephalitis virus

Ondersteuning

Primaire sponsor: ZonMW

Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measures the prevalence of the different TBDs tested in blood, urine, skin biopsy in a group of participants who develop fever within 4 weeks after tick-bite in the Netherlands, of whom other causes of the fever are excluded. This measurement will be compared to the prevalence of infection with the same TBPs between the different control

groups.

Toelichting onderzoek

Achtergrond van het onderzoek

The study is designed as a prospective case-control study. We aim to include 150 cases and 3 control groups consisting of 200 tick-bite, 200 general population and 200 healthy blood donor controls. During a one year follow-up we will acquire bodily materials – such as blood, urine and skin biopsy samples – ticks and questionnaires. The study investigates how often the TBPs *Anaplasma phagocytophilum*, *Babesia* species, *Borrelia miyamotoi*, *Neoehrlichia mikurensis*, *Rickettsia* species and tick-borne encephalitis (TBEV) can cause an acute febrile illness after tick-bite besides LB. We aim to determine the impact and seriousness of other tick-borne diseases (TBDs) in the Netherlands by measuring the prevalence and describing the clinical picture and the course of different other TBDs. In addition, the obtained materials will be used to develop diagnostic modalities to detect TBPs.

Doel van het onderzoek

We hypothesize that the other tick-borne pathogens are pathogenic and cause significant clinical disease in the Netherlands

Onderzoeksopzet

Materials: baseline, 4 and 12 weeks

Questionnaires: baseline, 3, 6, 9 and 12 months

Contactpersonen

Publiek

Amsterdam UMC
Dieuwertje Hoornstra

0205669111

Wetenschappelijk

Amsterdam UMC
Dieuwertje Hoornstra

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Cases (n=150)

- Subjects are ≥ 16 years old;
- Subjects report a tick-bite acquired within the last 2 months;
- Subjects report an objectified (measured rectally, orally, axillary or tympanic) fever (defined as $\geq 38.0^{\circ}\text{C}$) within the last 4 weeks, developed in the course of 4 weeks after tick-bite;
- Subjects live or stay in the Netherlands during the course of the study.

Controls (n=200)

- Subjects are ≥ 16 years old;
- Subjects report a tick-bite acquired within the last 2 months;
- Subjects frequency match to cases by gender, age, province of residence and month of tick-bite acquirement;
- Subjects live or stay in the Netherlands during the course of the study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Cases

- Subjects with evident signs or symptoms of another cause of the fever besides a TBD;
- Subjects unable to provide informed consent or do not have sufficient proficiency in the Dutch language.

Controls

- Subjects develop an objectified (measured rectally, orally, axillary or tympanic) temperature $> 37.3^{\circ}\text{C}$ within 4 weeks after the tick-bite;
- Subjects with evident signs or symptoms of a current infectious disease;
- Subjects unable to provide informed consent or do not have sufficient proficiency in the Dutch language.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	16-04-2018
Aantal proefpersonen:	350
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:	10-02-2021
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

NTR-new

Ander register

ID

NL9258

METC AMC : 2017_904

Resultaten