Ticking on Pandora's Box

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27838

Source
Nationaal Trial Register

Brief title
Pandora

Health condition

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

Sponsors and support

Primary sponsor: ZonMW
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

The secondary outcomes measures the long term sequelae and the clinical manifestations of the different TBD’s. This will be obtained from the questionnaires and information from the treating physicians and measured by laboratory tests, culture, molecular and serological analyses in both cases and control groups. An additional aim is to obtain clinical isolates of the different TBPs, and other materials from patients with well-defined other TBDs, for further research and development, improvement or validation of diagnostic tests.

Study description

Background summary

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.

Study objective

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

Study design

Materials: baseline, 4 and 12 weeks
Questionnaires: baseline, 3, 6, 9 and 12 months

Contacts

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Eligibility criteria

Inclusion criteria

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 ≥38.0°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.

Exclusion criteria

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°C within 4 weeks after the tick-bite;
• Subjects with evident signs or symptoms of a currant infectious disease;
• Subjects unable to provide informed consent or do not have sufficient proficiency in the Dutch language.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-04-2018
Enrollment:	350
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	10-02-2021
Application type:	First submission

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
NTR-new	NL9258
Other	METC AMC : 2017_904

Study results