Ticking on Pandora*s Box: a prospective case-control study into *other* tick-borne diseases.

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We aim to determine the impact and seriousness of other TBDs in the Netherlands by measuring the prevalence and describing the clinical picture and the course of different other TBDs.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON55432

Source
ToetsingOnline

Brief title
Pandora

Condition

- Other condition
- Bacterial infectious disorders

Synonym
Tick-borne diseases (TBD), Tick-borne pathogen (TBP).

Health condition

virale infectieziekten, Rickettsia infectieziekten, parasitaire aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: hard tick-borne relapsing fever, Ixodes ticks, Prospective case-control study, Tick-borne pathogens and diseases

Outcome measures

Primary outcome

1. 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.

2. 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 specialist(s) and measured by laboratory tests, PCR, serological and

culture analyses in both cases and controls

Secondary outcome

To obtain clinical isolates of the different TBPs, and other materials from

patients with well defined other TBDs, for further research and

development/improvement of diagnostic tests.

Study description

Background summary

Tick-borne pathogens (TBPs) other than Borrelia burgdorferi s.l. * the causative agent of Lyme Borreliosis - and tick-borne encephalitis virus (TBEV),

are common in Ixodes ticks in the Netherlands. How often these (potential) pathogens actually lead to disease is unknown and proper diagnostic tools are lacking. These problems lead to the initiation of the *Ticking on Pandora*s Box* study. This study investigates how often Borrelia miyamotoi, Anaplasma phagocytophilum, Neoehrlichia mikurensis, Rickettsia species or Babesia species can cause an acute febrile illness after tick-bite. In addition, the obtained materials will be used to diagnostic modalities to detect TBPs. The data and insights from our study can be used to develop new national guidelines on TBDs.

Study objective

We aim to determine the impact and seriousness of other TBDs in the Netherlands by measuring the prevalence and describing the clinical picture and the course of different other TBDs.

Study design

The current study is an prospective case-control study. Individuals who develop fever within 4 weeks after tick-bit are eligible for participation, if no other probable cause of the fever is found. Follow-up of participants is 12 months. From study participants digital questionnaires are obtained (at start and after 3, 6, 9 and 12 months), a urine sample is collected (at start), a skin biopsy is taken (at start, if a skin lesion is present and if separate consent is provided), and blood samples are taken (at start and after 4 weeks). Also, participants can send in the tick that has bitten them (at start). The tick and bodily materials are analyzed using existing and experimental tests for tick-borne pathogens (TBPs). The data from the questionnaires will be used to link symptoms to specific illnesses and to determine the course of these other TBDs. The results of this study will make important contributions to insights into the prevalence, clinical manifestation, diagnostics and possible treatment of TBPs in the Netherlands, which can be used for the modification of existing guidelines.

Study burden and risks

There is a minimal burden and negligible risk associated with study participation. Drawing blood can be accompanied with local pain and a hematoma, without the loss of functioning. Skin biopsy has a risk of local pain, a hematoma or a local skin infection. The local pain is reduced by local anesthesia (injection) and the risk for infection by local disinfection and sterile bandages for 48 hours after biopsy. Urine sampling has a minimal burden and does not bare any risks. The burden of time spent on the participation of this study is minimal (2-4 hours in one year).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Cases:
- Subjects are 16 years and older;
- Subjects report a tick-bite acquired in the last 2 months;
- Subjects develop fever (defined as * 38.0 °C) within 4 weeks after the tick-bite;
- The temperature is measured rectally, orally, axillary or tympanic;
- Subjects do not have evident signs or symptoms of another cause of the fever besides a TBD;
- Subjects live or stay in the Netherlands;
- Subjects are able to give informed consent and have a thorough command of the Dutch language., Controls:

- Subjects are 16 years and older;
- Subjects report a tick-bite acquired in the last 2 months;
- Subjects do not have a temperature > 37.3 °C within 4 weeks after the tick-bite;
- Subjects do not have evident signs or symptoms of any infectious disease;
- Subjects live or stay in the Netherlands;
- Subjects are able to give informed consent and have a thorough command of the Dutch language.

Exclusion criteria

Cases: Subjects, who
- Are 15 years or younger;
- Report a tick-bite acquired more than 2 months ago;
- Develop fever more than 4 weeks after tick-bite;
- Have not measured a temperature over 38.0 °C;
- Have evident signs and symptoms pointing towards another cause of the fever than a TBD;
- Live or stay outside of the Netherlands during the course of the study;
- Are unable to give informed consent or do not have a thorough command of the Dutch language., Controls: Subjects, who
- Are 15 years or younger;
- Report a tick-bite acquired more than 2 months ago;
- Develop a measured temperature * 37.3 °C within 4 weeks after the tick-bite;
- Have evident signs or symptoms of any infectious disease;
- Live or stay outside of the Netherlands during the course of the study;
- Are unable to give informed consent or do not have a thorough command of the Dutch language.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-06-2018
Enrollment:	800
Type:	Actual

Ethics review

Approved WMO

Date:	13-02-2018
Application type:	First submission
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	NL61446.094.17