Tick Test and Prophylaxis Proof

Published: 13-12-2012
Last updated: 19-03-2025

To determine the efficacy of antibiotic prophylaxis after a tick bite in the Dutch setting, in relation to tick infection, tick engorgement and attachment time.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON39797

Source
ToetsingOnline

Brief title
TT and PP

Condition

- Bacterial infectious disorders

Synonym
Borrelia infection, Lyme disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: antibiotics, Lyme disease, prophylaxis, tick bite

Outcome measures

Primary outcome

The primary study parameter is the prophylaxis efficacy, i.e. the relative risk (RR) reduction for developing Lyme disease after a tick bite and the NNT to prevent one case of Lyme disease. The tick screening results will be used to assess the reduction in NNT when only prescribing prophylaxis if the tick is infected and the engorgement or attachment time are above a certain threshold.

Secondary outcome

The number of participants that develop AEs in the month after taking the prophylaxis. Scores for epidemiological risk factors for acquiring tick bites and developing Lyme disease such as exposure to ticks in daily life, participants* activities when acquiring the tick bite, area of acquiring the tick bite, prevention of tick bites. Differences in NNT for children and adults.

Study description

Background summary

In the last 15 years, the number of cases of early Lyme disease in the Netherlands has tripled to 22,000 per year, posing an increasing public health burden. Antibiotic treatment of early Lyme disease is crucial as it can prevent the development of late and more severe disease stages. However, infections can initially remain undetected due to the diverse and often ambiguous nature of clinical manifestations of Lyme disease. Furthermore laboratory diagnostics are not always capable of detecting an early infection.
In the US, prophylactic antibiotic treatment after a tick bite has been shown to prevent most Lyme disease. It has not been investigated whether prophylaxis is effective in the Netherlands whereas transmission dynamics regarding ticks and Borrelia species are different from the US. With 1.1 million tick bites per year the recommendation of prophylaxis would result in very large numbers of

patients treated with prophylaxis.
For a future evidence-based guideline on prophylaxis, its efficacy in the Dutch setting should be investigated. It should also be investigated to what extent the NNT can be reduced by using tick-screening criteria (tick infection, tick engorgement and attachment time) to assess the risk of Lyme disease after each tick bite. If this tick-screening and subsequent preventive intervention procedure proves successful, most Lyme disease is preventable with minimal use of antibiotics.

Study objective

To determine the efficacy of antibiotic prophylaxis after a tick bite in the Dutch setting, in relation to tick infection, tick engorgement and attachment time.

Study design

This is a randomized controlled intervention study. A maximum of 4500 participants reporting a tick bite will be included and randomly treated with antibiotic prophylaxis or receive no further treatment. Participants in both groups will be followed up for the development of Lyme disease.

Intervention

The participants in the treatment group will take a single dose of doxycycline in a dosage of 200 mg for adults and children of 8 years and older and above 50 kg body weight; in a dosage of 4 mg/kg doxycycline for children of 8 years and older and below 50 kg body weight.

Study burden and risks

The participants in the treatment group may benefit of a possible effective prophylactic treatment. As with the use of any medicinal product, the participants may experience adverse events. Participants in the non-treatment group have no direct benefit but also no additional risk.
All participants (including those not receiving prophylaxis) send their ticks to the RIVM, and fill in online questionnaires at t=0, 1 wk and 1, 3, 6, 9, 12, 15 and 18 months after inclusion. Participants are advised to regularly check the place of the tick bite and consult their GP if an erythema migrans or other health complaints develop. This may have an indirect beneficial effect because participants are triggered to pay attention for manifestations of Lyme disease.

Contacts

Public
RIVM

Antonie van Leeuwenhoeklaan 9
Bilthoven 3721 MA
NL
Scientific
RIVM

Antonie van Leeuwenhoeklaan 9
Bilthoven 3721 MA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Persons who:
- are 8 yrs and older
- are not pregnant
- report a recent tick bite on the webportal Tekenradar.nl * i.e. at the moment of inclusion they are able to take prophylaxis within 72 hrs after removal of the tick.
- are willing to send the tick to the RIVM.

Exclusion criteria

Persons who:
- are unable to give informed consent or do not have a thorough command of the Dutch language.
- report other tick bites in the three months before inclusion.
- have a contra indication for treatment with doxycycline (including pregnancy and earlier allergic reactions to tetracyclines).
- are * at the moment inclusion * not able to take prophylaxis within 72 hours after removal of the tick

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-04-2013
Enrollment:	4500
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	doxycycline
Generic name:	doxycycline
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	13-12-2012
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	05-02-2013
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	03-06-2013
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	16-05-2014
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	22-05-2014
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27133
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2012-005101-51-NL
CCMO	NL42713.094.12
OMON	NL-OMON27133

Study results

Date completed:	09-12-2016
Actual enrolment:	3584