Tick Test & Prophylaxis Proof.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27133

Source
Nationaal Trial Register

Brief title
TT&PP

Health condition

Lyme disease (Lyme ziekte)
tick bite (tekenbeet)
prophylaxis (profylaxe)
antibiotics (antibiotica)

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Efficacy of prophylaxis, i.e. the relative risk (RR) reduction for developing Lyme disease after a tick bite and the Number Needed to Treat (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 Adverse Events 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

Antibiotic prophylaxis reduces the risk of Lyme disease after a tick bite in the Dutch setting, in relation to tick infection, tick
engorgement and attachment time.

Study design

After 1 week, 1 month, and every 3 months up to 18 months of f.u. the subjects are

requested to complete a questionnaire regarding symptoms of Lyme disease.

At week 1 and month 1 subjects in the treatment group are also asked about Adverse Events after antibiotic use.

Intervention

A single dose of 200 mg doxycycline for adults and children > 8 years and older (if body weight < 50 kg, the dose is adjusted to 4 mg/kg body weight) within 72 hours after tick removal.

The control group receives no treatment.

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

1. 8 yrs and older;

2. Not pregnant;

3. 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;

4. Willing to send the tick to the RIVM.

Exclusion criteria

1. Not able to give informed consent or do not have a thorough command of the Dutch language;

2. Report other tick bites in the three months before inclusion;

3. Contra-indication for treatment with doxycycline (including pregnancy and earlier allergic reactions to
tetracyclines);

4. Not able to take prophylaxis within 72 hours after removal of the tick at the moment inclusion.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2013
Enrollment:	2500
Type:	Actual

Ethics review

Positive opinion

Date:	18-04-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39797
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3787
NTR-old	NTR3953
CCMO	NL42713.094.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39797

Study results

Summary results
N/A