ISRCTN19325889 https://doi.org/10.1186/ISRCTN19325889

Single-investigator, randomized, double-blind, placebo-controlled trial of the efficacy and safety of oral antibiotics versus placebo in recurrent seropositive and seronegative Lyme disease

Submission date	Recruitment status	[_] Prospectively registered
02/03/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/03/2006	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/08/2011	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.lymeproject.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
100

Study information

Scientific Title

Study objectives
To evaluate the effectiveness and safety of oral antibiotics in treating recurrent seropositive and seronegative Lyme disease

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Western Institutional Review Board on 29/12/2000, reference number: 1391 WIRB

Study design
Single-investigator, randomized, double-blind, placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Recurrent Lyme disease

Interventions
Amoxicillin versus placebo

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Amoxycillin

Primary outcome measure
Clinical efficacy

Secondary outcome measures
1. Short form 36 (SF-36)
2. Review of symptom severity (ROSS)

Overall study start date
01/01/2001

Completion date
01/01/2004

Eligibility

Key inclusion criteria
1. 18 years or older to include the elderly
2. Both sexes
3. Outpatients
4. A signed consent must be obtained
5. Diagnostic criteria: Lyme disease symptomology as described by Logigian et al

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
108 seropositive and 108 seronegative

Key exclusion criteria
1. Signs: erythema migrans or physical sign (arthritis, Bells palsy, heart block, or meningitis) require treatment and therefore cannot be placed into a placebo arm
2. Inadequate initial treatment: patients not previously treated with at least 21 consecutive days with an antibiotic known to be effective for Lyme disease
3. Patients without any clinical evidence of Lyme disease
4. Patients anticipated to not able to return for follow-up examination
5. Patients with a type 1 hypersensitivity to penicillins

6. Pregnancy and postpartum or lactating female who is nursing
7. Other antibiotics: anticipated requirement of systemic antibiotics other than the study medication
8. Initial treatment failure: patients cannot be enrolled in the re-treatment subgroup if failing the first treatment
9. Medication failure: patients cannot be enrolled if they have a history of failing study medication

Date of first enrolment
01/01/2001

Date of final enrolment
01/01/2004

Locations

Countries of recruitment
United States of America

Study participating centre
175 Main Street
Mt. Kisco
United States of America
10549

Sponsor information

Organisation
Lyme Disease Practice and Research (USA)

Sponsor details
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Cameron@LymeProject.com

Sponsor type
Research organisation

Website
http://www.lymeproject.com

Funder(s)

Funder type
Research organisation

Funder Name
Lyme Disease Association and First Medical Associates

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration