

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

02/03/2006

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

22/03/2006

Overall study status

Completed

☐ Statistical analysis plan

☐ Results

Last Edited

16/08/2011

Condition category

Infections and Infestations

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

Clinical efficacy

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

Funder(s)

Funder type
Research organisation

Funder Name
Lyme Disease Association and First Medical Associates

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes