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Phase II, randomised, single-center, open-label study of the efficacy of Ketek® in the treatment of Lyme disease

Submission date
20/03/2005

Recruitment status
No longer recruiting

Registration date
29/03/2005

Overall study status
Completed

Last Edited
13/06/2014

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
876N

Study information

Scientific Title

Study objectives
This study will examine the hypothesis that Ketek® is as effective as amoxicillin in treating Lyme Disease (LD). The validity of our in vitro infection model will be strengthened by measuring telithromycin maximal plasma concentration and the area under the concentrationtime curve (AUC). Patients completing the duration study will be allowed to enter long-term open-label follow-up studies. These proof of concept findings would lead to at least one large multicenter confirmatory, double-blind, randomised, comparator, parallel-group Phase III study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Ketek® versus Amoxicillin (comparator)

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Ketek, Axoxicillin

Primary outcome(s)
Success using clinical impression

Key secondary outcome(s))
1. Short Form health survey (SF-36)
2. Review Of Symptoms Scale (ROSS)

Completion date
30/04/2007

Eligibility

Key inclusion criteria
Patients with clinically suspected recurrent LD evaluated in a primary care setting in a Lyme disease endemic area, will be eligible for participation in the study if they meet the selection criteria:
1. Clinically documented disease described by Asch et al. and Logigian et al.
2. History of previous oral and intravenous antibiotics
3. Age 18 years or older to include the elderly (no upper age limits will be established)
4. Both sexes
5. A written informed consent document regarding the experimental nature of the study
6. Ability to comply with the protocol follow-up
7. Women of childbearing potential must be using a medically acceptable method of birth control and have a negative serum Human Chorionic Gonadotropin (HCG) pregnancy test result at the initial screening visit

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Exclusion criteria will be limited to secure inclusion of as many patients as possible, thus avoiding difficulties in generalising the results. Patients will be excluded from the study if:
1. They have not previously been treated for at least 21 days with an antibiotic known to be effective for Lyme disease
2. They are not able to return for follow-up
3. They have a history of allergies to erythromycin, macrolides, or Ketek®
4. They have a history of allergies to both amoxicillin and doxycycline
5. They are pregnant or are a postpartum/lactating female who is nursing

Date of first enrolment
01/09/2005

Date of final enrolment
30/04/2007

Locations

Countries of recruitment
United States of America

Study participating centre
175 Main Street
New York
United States of America
10549

Sponsor information

Organisation
First Medical Associates (USA)

Funder(s)

Funder type
Industry

Funder Name
Not provided at time of registration

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes