ISRCTN03563617 https://doi.org/10.1186/ISRCTN03563617

# 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

### 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 measure
Success using clinical impression

### Secondary outcome measures
1. Short Form health survey (SF-36)
2. Review Of Symptoms Scale (ROSS)

### Overall study start date
01/09/2005

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
90

### 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)

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### Sponsor type
Industry

## Funder(s)

### Funder type

Industry

**Funder Name**
Not provided at time of registration

# 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