

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

<b>Submission date</b> 20/03/2005	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 29/03/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 13/06/2014	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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)

**Sponsor details**

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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