A randomized, double blind, placebo-controlled, phase 2a study of the efficacy, safety and pharmacokinetics of MLN3897 in patients with rheumatoid arthritis taking methotrexate.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27198

Source
NTR

Brief title
N/A

Health condition

Rheumatoid arthritis (RA)

Sponsors and support

Primary sponsor: Millennium Pharmaceuticals Inc.

Intervention

Outcome measures

Primary outcome

1. Percentage of ACR20 response at day 84 in MLN3897 vs. placebo treated patients;

2. Safety assessments.

Secondary outcome

1. DAS28 response;

2. ACR50/ACR70 response;

3. Change in individual components of ACR criteria;

4. Time to ACR20 response.

Study description

Background summary

Study Title:

A ranomized, Double-Blind, Placebo-controlled, Phase 2a study of the Efficacy, safety and pharmacokinetics of MLN3897 in Patients with active Rheumatoid Arthritis (RA).

Primary Objectives:

To evaluate:

-The ability of MLN3897 to modify signs and symptoms of RA

-The safety and tolerability of MLN3897 in combination with methotrexate

-the pharmacokinetic/pharmacodynamic profile of MLN3897 in the RA population
Number of patients: 186.

Study population:

The study population will consist of male and female patients aged 18-70 years who have 1) RA with a duration of at least 6 months (based on ACR criteria); 2) an RA Global Functional Class of I,II or III; 3) at least 6 tender and 6 swollen joints at the time of randomization; and 4) at least 2 of 3 criteria (morning stiffness duration >45 minutes, CRP>15, ESR ¡Ý28 mm/hr). Patients must be taking methotrexate for a minimum of 6 months prior to screening. Eligible patients will receive MLN3897 or placebo for 84 days. After the treatment period,

there is a 30-day follow-up period.

Study objective

MLN3897 is safe and improves signs and symptoms of rheumatoid arthritis.

Study design

N/A

Intervention

12 week treatment with MLN3897 or placebo, taken orally once daily.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 18-70;

2. Meeting ACR criteria for RA;

3. RA Global Functional Class I,II or III;

4. Taking MTX for a minimum of 6 months before screening, dose stable 3 months;

5. No more than 10 mg/day prednisone/equivalent;

6. Stable use (if on) NSAIDs, at least 2 weeks;

7. Willing/able to comply to the protocol;

8. Female of childbearing potential must not be pregnant, or breastfeeding;

9. Females of childbearing potential and all males must use two accepted forms of contraception for the duration of the study;

10. Have at least 6 tender and 6 swollen joints plus two of the following: morning stiffness >45 minutes, ESR >28 mm/hr, CRP >1.5 mg/dl.

Exclusion criteria

1. Use of any other DMARDS than MTX concomitantly or within one month prior to enrollment (in case of leflunomide, 3 months prior to enrollment or washout with cholestyramine);

2. Currently being treated with TNF-antagonists or other biologicals (washout period 8 weeks);

3. TB infection;

4. Have received investigational drug one month prior to day1;

5. Have received intra-articular or systemic injection with corticosteroids within one month prior to screening;
6-26 summary: have any other condition or increased risk of a condition or concomitant use of medication incompatible with the study (including infections, liver and kidney diseases, cardiac conditions/arrythmia, etc.) or have a history of cancer, except for distant history of cured ca. in situ of the cervix or BCC.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2006
Enrollment:	186
Type:	Actual

Ethics review

Positive opinion

Date:	29-12-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL842
NTR-old	NTR856
Other	: N/A
ISRCTN	ISRCTN49455679

Study results

Summary results
N/A