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

Submission date
22/01/2007

Registration date
22/01/2007

Last Edited
15/01/2021

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
NL842, NTR856

Study information

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

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Medical Ethical Committee on the 16th November 2006, amendment one approved on the 29th November 2006 (ref: 06-139).

Primary study design
Interventional

Study design
Randomised, placebo controlled, parallel group, double blinded multicentre trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rheumatoid arthritis

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

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
MLN3897, methotrexate

Primary outcome(s)
1. Percentage of ACR20 response at day 84 in MLN3897 versus placebo treated patients
2. Safety assessments

Key secondary outcome(s)
1. Disease Activity Scale (DAS28) response
2. ACR50/ACR70 response
3. Change in individual components of ACR criteria
4. Time to ACR20 response

Completion date
01/09/2007

Eligibility

Key inclusion criteria
1. Age 18 to 70
2. Meeting American College of Rheumatology (ACR) criteria for Rheumatoid Arthritis (RA)
3. RA Global Functional Class I,II or III
4. Taking MethoTreXate (MTX) for a minimum of six months before screening, dose stable three months
5. No more than 10 mg/day prednisone/equivalent
6. Stable use of (if on) Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), for at least two 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 six tender and six swollen joints plus two of the following:
a. morning stiffness more than 45 minutes
b. Erythrocyte Sedimentation Rate (ESR) more than 28 mm/hr
c. C-Reactive Protein (CRP) more than 1.5 mg/dl

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Total final enrolment
191

Key exclusion criteria
1. Use of any other Disease Modifying Anti-Rheumatic Drugs (DMARDs) than MTX concomitantly or within one month prior to enrolment (in case of leflunomide, three months prior to enrolment or washout with cholestyramine)
2. Currently being treated with Tumour Necrotising Factor (TNF)-antagonists or other biologicals (washout period eight weeks)
3. Tuberculosis (TB) infection
4. Have received investigational drug one month prior to day one
5. Have received intra-articular or systemic injection with corticosteroids within one month prior to screening
6 to 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 carcinoma in situ of the cervix or Basal Cell Carcinoma (BCC).

Date of first enrolment

01/09/2006

Date of final enrolment
01/09/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Center (AMC) (The Netherlands)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Industry

Funder Name
Millennium Pharmaceuticals Inc (USA)

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?
Results article	results	01/12/2009	15/01/2021	Yes	No