A study of ARA 290 for treating rheumatoid arthritis.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22511

Source
NTR

Brief title
ARARA

Health condition

rheumatoid arthritis
reumatoide artritis
reuma

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

Weekly measurements of:

1. Disease activity, measured by the disease activity score: 'original DAS';

2. Functionaly ability, measured by the Health Assessment Questionaire (HAQ) disability index;

3. Systemic inflammation: ESR, CRP.

Secondary outcome

Weekly assessment of:

Tolerability, using blood investigation and physical examination.

Study description

Background summary

ARARA is an open label phase II study investigating the effect of ARA290 on disease activity, functional ability and systemic inflammation in patients with active rheumatoid arthritis. Twelve patients will receive an intravenous dose (2mg) of ARA290 once or thrice weekly depending on randomization, during 4 weeks. During treatment, they will also continue the use of their own disease modifying anti rheumatic drug (DMARD). Previous or current use of a biologic agent will not be allowed. Efficacy and tolerability will be evaluated weekly.

Study objective

ARA290 will reduce disease activity in rheumatoid arthritis.

Study design

1. Weekly assessment of disease activity, functional ability, systemic inflammation and tolerability from start treatment until one week after end of treatment;

2. Extra assessment of all primary outcomes one month after end of treatment and when disease activity flares.

Intervention

Thrice or once (depending on randomization) weekly intravenous dose of study drug ARA 290, 2 mg bolus, for 4 weeks.

Contacts

Public
Leiden University Medical Center (LUMC),
Department of Rheumatology,
C1-39,
P.O. Box 9600
C.F. Allaart
Leiden 2300 RC
The Netherlands
+31 (0)71 5263598
Scientific
Leiden University Medical Center (LUMC),
Department of Rheumatology,
C1-39,
P.O. Box 9600
C.F. Allaart
Leiden 2300 RC
The Netherlands
+31 (0)71 5263598

Eligibility criteria

Inclusion criteria

1. Diagnosis of RA, classified by ARA (American Rheumatism Association) 1987 revised criteria;

2. Active disease at screening and baseline: 6/68 tender and 6/66 swollen joints and either an erythrocyte sedimentation rate (ESR) of >=28 mm/hr or C-reactive protein (CRP)> 10 mg/l;

3. Written informed consent.

Exclusion criteria

1. Current or previous treatment with biological agent;

2. Clinically relevant abnormal laboratory results, ECG, vital signs, or physical findings other than conditions related to rheumatoid arthritis (as judged by the investigator);

3. Pregnancy or wish to become pregnant during the study, or childbearing potential without adequate contraception;

4. Participation in an investigational drug trial, current or in the 3 months prior to

administration of the initial dose of study drug or more than 4 times per year;

5. Use of erythropoietin;

6. Inability to follow the protocol and to comply with the follow up requirements;

7. Clinically relevant abnormal history of physical and mental health other than conditions related to rheumatoid arthritis, as determined by medical history taking (as judged by the investigator) or any other condition that in the opinion of the investigator would complicate or compromise the well being of the subject.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2011
Enrollment:	14
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-10-2010
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	NL2460
NTR-old	NTR2577
Other	METC LUMC : P10.236
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
Brines M, Cerami A. Discovering erythropoietin's extra-hematopoietic functions: biology and clinical promise. Kidney Int 2006; 70(2):246-50.