A study of ARA 290 for treating rheumatoid arthritis.

Gepubliceerd: 21-10-2010 Laatst bijgewerkt: 18-08-2022

ARA290 will reduce disease activity in rheumatoid arthritis.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22511

Bron
NTR

Verkorte titel
ARARA

Aandoening

rheumatoid arthritis
reumatoide artritis
reuma

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: Fund=initiator=sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

ARA290 will reduce disease activity in rheumatoid arthritis.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2011
Aantal proefpersonen:	14
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-10-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2460
NTR-old	NTR2577
Ander register	METC LUMC : P10.236
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

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