Een dubbelblind, placebo-gecontroleerd fase 2 onderzoek naar de effecten van ARA 290 op neuropathische symptomen in patiënten met type 2 diabetes.

Gepubliceerd: 14-02-2013 Laatst bijgewerkt: 13-12-2022

ARA 290 improves neuropathic symptoms in patients with type 2 diabetes.

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

Samenvatting

ID

NL-OMON21147

Bron
Nationaal Trial Register

Verkorte titel
ARAND

Aandoening

type 2 diabetes mellitus
small fiber neuropathy (dunne vezel neuropathie)
pain (pijn)
eye exams (oogonderzoek)
skin biopsy (huidbiopten)

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: Araim Pharmaceuticals

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Collection of adverse events, serious adverse events, and laboratory parameters;
2. Change in hemoglobin A1c at day 28 and 56 compared to baseline;
3. Change in the scores of the Small Fiber Neuropathy Screening List, Pain Detect, and RAND-36 (pain and physical function components) at days 28, 56, 84, and 112 compared to screening.

Toelichting onderzoek

Achtergrond van het onderzoek

ARA 290 has been demonstrated to be a neuroprotective and neurotrophic agent in a variety of preclinical in vitro and in vivo models. We will determine the effect of ARA 290 on neuropathic symptoms in patients with type 2 diabetes. Patient will be enrolled in one single center.

Doel van het onderzoek

ARA 290 improves neuropathic symptoms in patients with type 2 diabetes.

Onderzoeksopzet

Weekly questionnaires and follow-up for 12 weeks.

Onderzoeksproduct en/of interventie

ARA 290 subcutaneous during 28 days or placebo.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Established diagnosis of diabetes mellitus type 2;

2. Screening HbA1c between 7.5 % and 10 % inclusive;

3. Spontaneous discomfort level of 6 or greater on Pain Now (Pain Detect; 0 (least discomfort)-10 (worst discomfort)), OR;

4. Small fiber neuropathy screening list score (SFNSL) > 22, AND;

5. Quantitative sensory testing shows allodynia and altered temperature thresholds, OR;

6. Discomfort defined as distal pain/discomfort plus one of the following:

A. Paresthesia;

B. Burning/painful feet worsening at night;

C. Intolerance of sheets or clothes touching the legs or feet.

7. Be able to read and understand the written consent form, complete studyrelated procedures, and communicate with the study staff;

8. Be willing to comply with study restrictions;

9. Be willing to check in with the study center via the telephone;

10. Between 18 and 70 years of age (inclusive);

11. Body Mass Index (BMI) < 40 kg/m2 (inclusive);

12. If female of childbearing potential, a negative urine pregnancy test at screening and acceptable contraception will be maintained during the screening and dosing period and 1 month beyond. Acceptable contraception consists of hormonal methods such as oral, implantable, injectable, or
transdermal contraceptives for a minimum of 1 full cycle (based on the patient's usual menstrual cycle period) before study entry, intrauterine device (IUD), or double-barrier method (condoms, sponge, diaphragm, or vaginalring with spermicidal jellies or cream);

13. Able to complete self-administered questionnaires (RAND-36, SFNSL, Pain Detect);

14. Refrigerator at home for storage of study medication.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Clinically relevant abnormal history of physical and mental health other than conditions related to diabetes, as determined by medical history taking (as judged by the investigator);

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

3. Known clinically relevant abnormalities in ECG (as judged by the investigator);

4. Episodes of significant hypoglycemia (as judged by the investigator);

5. Illicit drug abuse or excessive alcohol consumption (as judged by the investigator);

6. History of serious malignancy (as judged by the investigator);

7. History of fainting (as judged by the investigator);

8. History of severe allergies, or has had an anaphylactic reaction or significant intolerability to prescription or non-prescription drugs or food (as judged by the investigator);

9. Subjects that received a vaccination or immunization within the month prior to screening;

10. Anti-TNF therapy or other biological anti-inflammatory agents administered within the 6 months prior to screening;

11. Use of erythropoiesis stimulating agents within the two months prior to screening or during the trial;

12. Participation in an investigational drug trial in the 3 months prior to administration of the

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

13. Inadequate venous accessibility as judged by clinicians (physician or nurse);

14. Inability or unwillingness to self-administer ARA 290 via subcutaneous injections (or not have access to home health care for assistance in administration);

15. If female, pregnant or breast-feeding;

16. Any other condition that in the opinion of the investigator would complicate or compromise the study, or the well being of the patient.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2013
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-02-2013
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	NL3688
NTR-old	NTR3858
Ander register	METC LUMC : P12.293
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A