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

No registrations found.

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

Summary

ID

NL-OMON21147

Source
Nationaal Trial Register

Brief title
ARAND

Health condition

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

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Araim Pharmaceuticals

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. Change in quantitative sensory testing at day 28 and day 112 versus baseline;

2. Change in intra epidermal nerve fiber density at day 28 and day 112 versus baseline;

3. Change in the 6 minute walk test at day 28 versus baseline;

4. Change in visual acuity at day 28 versus baseline;

5. Change in heart rate variability (R-R and QT intervals) at day 28 versus baseline;

6. Change in retinal thickness at day 28 versus baseline as determined by optical coherence tomography;

7. Change in cornea fiber density or length at day 28 and day 112 versus baseline as determined by cornea confocal microscopy;

8. Additionally, the effect of ARA 290 on glucose control, C reactive protein, and microalbuminuria in patients with diabetes will be assessed.

Study description

Background summary

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.

Study objective

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

Study design

Weekly questionnaires and follow-up for 12 weeks.

Intervention

ARA 290 subcutaneous during 28 days or placebo.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2013
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion Date:	14-02-2013
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	NL3688
NTR-old	NTR3858
Other	METC LUMC : P12.293
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A