Immuun interventie met tolerogene dendritische cellen (DC) in type 1 diabetes. Eerste klinische veiligheidsstudie genaamd D-sense

Gepubliceerd: 02-10-2015 Laatst bijgewerkt: 13-12-2022

Diabetes Mellitus type 1 is an autoimmune disease that cannot be cured. Complications due to insufficient regulation of blood glucose by exogenous insulin reduce life expectancy and quality of life. Proinsuline-loaded Tolerogenic DCs are induce...

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

Samenvatting

ID

NL-OMON21892

Bron
NTR

Verkorte titel
D-sense

Aandoening

Diabetes Mellitus, Type 1
Immunotherapy
Dendritic cells
Safety
Type 1 diabetes
Immunotherapie
Dendritische cellen
Veiligheid

Ondersteuning

Primaire sponsor: Leiden Universitu Medical Center

Overige ondersteuning: FP7, NAIMIT

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

a. Primary safety endpoints
Occurrence of any of the following safety and feasibility concerns:
- hypersensitivity reaction grade ¡Ý 3 to PIpepTolDC product upon intradermal injections
- disease exacerbation as defined by ¡Ý 40% decrease of stimulated C-peptide production compared to baseline
- any infectious complications requiring systemic medical treatment
- diagnosis of any new disease associated with autoimmunity
- diagnosis of new malignancy
- any other serious adverse event
b. Primary feasibility endpoints
- failure to complete a successful leukapheresis procedure
- failure to isolate sufficient numbers of mononuclear cells by leukapheresis for PIpepTolDC production
- failure to generate the required dose of PIpepTolDCs
- any event that prevents the protocol or follow up to be executed as planned.

Toelichting onderzoek

Doel van het onderzoek

Diabetes Mellitus type 1 is an autoimmune disease that cannot be cured. Complications due to insufficient regulation of blood glucose by exogenous insulin reduce life expectancy and quality of life. Proinsuline-loaded Tolerogenic DCs are induce antigen-specific Tregs and thereby inhibit autoimmune destruction of beta-cells.

Onderzoeksopzet

weeks: 4, 8, 12, 24

Onderzoeksproduct en/of interventie

Two intradermal injections of PIpepTolDCs (5x 10e6, 10x 10e6 or 20 x 10e6/ injection in 3 patients each) with a 28-day interval.

Contactpersonen

Publiek

P.O.Box 9600
J.J. Zwaginga
Albinusdreef 2
Leiden 2300 RC
The Netherlands

Wetenschappelijk

P.O.Box 9600
J.J. Zwaginga
Albinusdreef 2
Leiden 2300 RC
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Age 18-50 years;

• Diagnosis of type 1 Diabetes Mellitus at least 18 months (dated from the first insulin injection);

• Adequate self-assessment of blood glucose values, and recording of glucose values and administered insuline
doses as deemed sufficient by the patient¡¯s physician

• Stable glycemic control according to the patient¡¯s physician

• Possession of *0401 allele at the HLA-DRB1 gene locus;

• Written and witnessed informed consent.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

• Use of immunosuppressive or immunomodulatory therapies, including systemic steroids within 1 month prior to
enrolment and/or prior monoclonal antibody therapy of any type given for any indication at any time;

• Immunisation with live or killed vaccines or allergic desensitization procedures less than 1 month prior to
enrolment;

• History of disease associated with autoimmunity or inflammatory disorders other than type 1 Diabetes Mellitus;

• History of malignancy;

• Male or female patients who are fertile and are unwilling to use adequate contraception at least 3 months prior to
the first administration of PIpepTolDCs until at least 60 days following the last administration of PIpepTolDCs;

• Recent (< 3 months) fasting insulin C-peptide > 200 pmol/L;

• Peak insulin C-peptide < 200 pmol/L after stimulation with Mixed Meal Tolerance Tests (MMTT).

• Recent (< 3 months) HbA1c > 64 mmol/ mol.

• No positive beta-cell autoantibody or antibodies (eligible autoantibodies: anti IAA, GADA or dIA-2A)

• Female patients who are pregnant or breastfeeding;

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2015
Aantal proefpersonen:	9
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-10-2015
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	NL5425
NTR-old	NTR5542
Ander register	: ABR48984

Resultaten