Endoscopic application of pulsed electric fields by the DyaMX system® for duodenal Mucosal regeneration for elimination of INsulin in the treatmENT of type 2 diabetes: a first in human safety, feasibility and efficacy study

Gepubliceerd: 18-05-2021 Laatst bijgewerkt: 19-08-2024

Metabolic syndrome is a cluster of conditions that are associated with insulin resistance, hyperinsulinemia and type 2 diabetes (T2D). Pathophysiological conditions characterized by insulin resistance and hyperinsulinemia can lead to several, often...

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

Samenvatting

ID

NL-OMON21610

Bron
NTR

Verkorte titel
EMINENT

Aandoening

Diabetes type 2

Ondersteuning

Primaire sponsor: Endogenex Inc.
Overige ondersteuning: Endogenex Inc. and Amsterdam UMC location AMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The safety endpoint is the incidence rate of the following events at 6 weeks, 6 months, and 12 months post-procedure:
- All procedure and device-related Serious Adverse Events (SAEs) and Unanticipated Adverse Device Effects (UADEs)
- All SAEs
- Number of hypoglycemic events (self-measured blood glucose level of 3.1 mmol/L) or requiring 3rd party assistance)

Toelichting onderzoek

Achtergrond van het onderzoek

The objective of this first-in-human study is to evaluate the safety, feasibility, and efficacy of pulsed electric field (PEF) induced duodenal mucosal regeneration (DMR) by the DyaMX system combined with a GLP-1 receptor agonist (Semaglutide, Ozempic) in subjects with insulin-dependent type 2 diabetes mellitus and an adequate beta cell reserve. The aimed effect is an adequate or improved glucose regulation without the need for insulin therapy. Secondary effects include improved cardiovascular, hepatological, and metabolic parameters.

Doel van het onderzoek

Metabolic syndrome is a cluster of conditions that are associated with insulin resistance, hyperinsulinemia and type 2 diabetes (T2D). Pathophysiological conditions characterized by insulin resistance and hyperinsulinemia can lead to several, often overlapping, metabolic disease, including T2D, non-alcoholic fatty liver disease (NAFLD), cardiovascular disease and polycystic ovarian disease. T2D can, however, be effectively treated by bariatric surgery. Subjects undergoing Roux-en-Y gastric bypass surgery demonstrate major improvements in glycaemic control and metabolic and cardiovascular health. This suggests an important role for the duodenum. The important role of the duodenal mucosa is highlighted by specific endoscopic procedures to treat T2D and concomitant metabolic diseases.

Onderzoeksopzet

After a positive screening visit, a baseline visit is scheduled within 3 weeks. The PEF-DMR procedure is scheduled within 3 weeks after the baseline visit. Follow-up visits are scheduled at 3 days, and 4, 8, 12, 24, 36, and 48 weeks after the procedure. At 1,2,7,14 and 21 days after the procedure a phone call is scheduled. After 3 and 28 days, a follow-up endoscopy is

performed. MRI liver fat fraction is scheduled at baseline, 24 and 48 weeks follow-up.

Onderzoeksproduct en/of interventie

Pulse Electric Field (PEF) induced duodenal mucosal regeneration (DMR) is a minimally invasive endoscopic procedure that uses the Endogenex device (Endogenex Inc., Plymouth, MN, USA) to deliver PEF to the duodenum. The treatment is non-thermal and does not require mucosal lifting for protecting submucosal tissue. PEF induces mucosal renewal via cell apoptosis and subsequent rapid regeneration.

Contactpersonen

Publiek

Amsterdam UMC
Jacques Bergman

020-5665383

Wetenschappelijk

Amsterdam UMC
Jacques Bergman

020-5665383

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Diagnosed with type 2 diabetes mellitus
2. 28 -75 years of age
3. Treatment with long acting insulin ≤ 10 years
4. On daily long acting insulin dose ≤ 1 U/kg
5. No specific restrictions regarding concomitant other glucose lowering drugs
6. BMI ≥ 24 and ≤ 40 kg/m2
7. HbA1c ≤ 8.0% (64 mmol/mol)
8. Fasting C-peptide ≥ 0.5 nmol/L (1.5 ng/ml)
9. Fasting Plasma Glucose ≥ 10 mmol/L

10. Willing to comply with study requirements and able to understand and comply with informed consent
11. Signed informed consent form

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Diagnosed with Type 1 Diabetes or with a history of ketoacidosis
2. Current use of multiple daily doses insulin or insulin pump.
3. Known autoimmune disease, as evidenced by a positive Anti-GAD test, including Celiac disease, or pre-existing symptoms of systemic lupus erythematosus, scleroderma or other autoimmune connective tissue disorder
4. Previous GI surgery that could affect the ability to treat the duodenum such as subjects who have had a Bilroth 2, Roux-en-Y gastric bypass, or other similar procedures or conditions
5. History of chronic or acute pancreatitis
6. Known active hepatitis or active liver disease
7. Symptomatic gallstones or kidney stones, acute cholecystitis or history of duodenal inflammatory diseases including Crohn’s Disease and Celiac Disease
8. History of coagulopathy, upper gastro-intestinal bleeding conditions such as ulcers, gastric varices, strictures, congenital or acquired intestinal telangiectasia
9. Use of anticoagulation therapy (such as phenprocoumon and acenocoumarol) and novel oral anticoagulants (such as rivaroxaban, apixaban, edoxaban and dabigatran) which cannot be discontinued for 7 days before and 14 days after the procedure
10. Use of P2Y12 inhibitors (clopidogrel, pasugrel, ticagrelor) which cannot be discontinued for 14 days before and 14 days after the procedure. Use of aspirin is allowed.
11. Unable to discontinue NSAIDs (non-steroidal anti-inflammatory drugs) during treatment through 4 weeks post procedure phase
12. Taking corticosteroids or drugs known to affect GI motility (e.g. Metoclopramide)
13. Receiving weight loss medications such as Meridia, Xenical, or over the counter weight loss medications
14. Persistent Anemia, defined as Hgb < 6.2 mmol/l
15. Known history of cardiac arrythmia
16. Significant cardiovascular disease, including known history of valvular disease or myocardial infarction, heart failure, transient ischemic attack, or stroke within 6 months prior to the screening visit
17. With any implanted electronic devices or duodenal metallic implants
18. eGFR or MDRD < 30 ml/min/1.73m^2
19. Active systemic infection
20. Active malignancy within the last 5 years
21. Not potential candidates for surgery or general anesthesia
22. Active illicit substance abuse or alcoholism
23. Pregnancy or wish getting pregnant in next year
24. Participating in another ongoing clinical trial of an investigational drug or device
25. Any other mental or physical condition which, in the opinion of the Investigator, makes the subject a poor candidate for clinical trial participation

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2021
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	18-05-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54013
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9482
CCMO	NL76776.018.21
OMON	NL-OMON54013

Resultaten