Digma System Study - Safety, efficacy and performance of the Digma system for the treatment of type 2 diabetes - sham control study

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To evaluate the safety and performance of the Digma System for duodenal submucosal ablation in patients with type 2 diabetes in comparison to baseline and to sham control.

Ethical review	Approved WMO
Status	Completed
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON52062

Source
ToetsingOnline

Brief title
Digma System Study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes type 2

Research involving
Human

Sponsors and support

Primary sponsor: Digma Medical Ltd
Source(s) of monetary or material Support: Digma

Intervention

Keyword: ablation, diabetes, duodenal, submucosal

Outcome measures

Primary outcome

Primary Safety endpoint

• Incidence of procedure related SAEs and AEs within 7 days post

procedure.

Primary Efficacy Endpoint:

Primary efficacy endpoint at 24 weeks.

• Change in HbA1c level compared with baseline

• Change in HbA1c level compared with sham control

Secondary outcome

Secondary Safety endpoints

* Incidence of procedure related SAEs and AEs 4 weeks, 12 weeks

and 24 weeks post procedure.

Change in glycaemic, metabolic, hepatic and cardiovascular parameters, compared

with baseline and sham control

Study description

Background summary

The incidence of type 2 diabetes is increasing in a rapid pace. Patients with type 2 diabetes have a high risk of cardiovascular complications.

There are several types of pharmacological agents for the treatment of type 2 diabetes. They however, don't target the root cause of the disease. Moreover, glucose control has not improved in patients with type 2 diabetes over the past years.
Studies out of the field of bariatric surgery report that the duodenum plays an important role in glucose homeostasis. It is hypothesized that the duodenal mucosa changes in people with type 2 diabetes. The Revita System for duodenal ablation has shown that was safe and effective in improving glycaemic control and metabolic parameters in patients with type 2 diabetes.
This new Digma EGM procedure also elicits regeneration of the duodenal mucosa. We want to investigate te safety, feasibility and effectiveness of this procedure in patients with type 2 diabetes, on oral medication.
See section 1 of the protocol for more information.

Study objective

To evaluate the safety and performance of the Digma System for duodenal submucosal ablation in patients with type 2 diabetes in comparison to baseline and to sham control.

Study design

The study consists of 2 parts.
Study Part A is 24 weeks randomized, parallel assignment, double blinded study
Study Part B is a 24 weeks unblinded study

Study Part A:
Active comparator: Endoscopic Glycemic Management (EGM) Procedure
EGM Procedure will include the endoscopic procedure for the creation of ablations in the submucosa layer in the duodenum.
Sham comparator: Sham Procedure (Sham)
Sham Procedure (Sham) will include the endoscopic procedure without the creation of ablations in the submucosa layer in theduodenum.

Study Part B:
Active comparator: will be followed for an additional 24 weeks
Cross over: Sham comparator will now undergo EGM Procedure and will be followed for 24 weeks

Intervention

Digma System is a laser based endoscopic device for the ablation of the duodenal submucosa. The device is composed of two (2) components: 1) laser generator unit, 2) a disposable endoscopic catheter (*Digma Catheter*).

Study burden and risks

The burden and risk mainly consist out of extra time spent in comparison to standard treatment, the DMR or sham procedure andthe risks of medical evaluation, including venapunctures and biopsy.
See the protocol, section 6 for more information on measure that were taken to minimalize risks for study participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Subjects who are >= 18 years and <= 75 years of age
2. Type 2 diabetes diagnosis with disease duration <=15 years
3. HbA1c at 8.0%-10.5%
4. Subjects, in the opinion of the investigator, who have been unsuccessfully managed with lifestyle (diet/exercise) counselling and are taking >= two anti-diabetes medication (orals or injectable

GLP-1), other than insulin, at >= half the maximum recommended dose or at the maximally tolerated dose for at least 3 months
5. Fasting plasma glucose level at >=125 mg/dL
6. BMI 25-35 kg/m2
7. Negative pregnancy or nursing status and agreement to use of contraceptives during participation for women with childbearing potential
8. Ability to provide written informed consent
9. Willing and able to comply with follow-up requirements.

Exclusion criteria

1. Type 1 diabetes diagnosis and/or history of diabetic ketoacidosis and/or glutamic acid decarboxylase autoantibodies test (GAD Ab+) positive
2. Fasting Serum C peptide <1 ng/ml
3. Fasting Triglycerides > 400 mg/dL
4. Currently using or having used Insulin in the past (other than for hospitalization or acute illness)
5. Currently using Amylin analogs
Hepatic and Gastrointestinal:
6. History of, or currently symptomatic for, pancreatitis, gallbladder/gallstones pathologies
7. Any known hepatic abnormality other than non-alcoholic fatty liver abnormality
8. Alcohol consumption >30 gram/day)2 glasses of beer or wine/day)
9. AST >5x upper limit of normal (ULN) and/or ALT >5x ULN
10. Serum albumin < 3.2 g/dL

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	26-01-2023
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	18-05-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-07-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-11-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL76710.018.21

Study results

Date completed: 16-02-2023

Actual enrolment: 3

Summary results
Trial ended prematurely