An advanced configuration (the third generation) of the DIAMOND System for the treatment of T2DM patiënts- A randomized double blind study "Ruby Study".

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

Summary

ID

NL-OMON37628

Source
ToetsingOnline

Brief title
RUBY Study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Appetite and general nutritional disorders

Synonym
diabetes, T2DM

Research involving
Human

Sponsors and support

Primary sponsor: MetaCure Limited
Source(s) of monetary or material Support: Metacure;sponsor van de studie

Intervention

Keyword: Diabetes Mellitus, Endocrine System Diseases, Gastric pacing, Metabolic Diseases, Type 2

Outcome measures

Primary outcome

The difference, at 12 months, in HbA1c change from baseline, in patients with

an active DIAMOND System.

Secondary outcome

1. HbA1c reduction in 6 months from baseline for patients with an active

operating DIAMOND System

2. To detect differences in the pattern of meal related release of GI hormones.

3. The difference in metabolic parameters at 6 and 12 months from baseline

between two arms.

4. The effect of TG level at basline on treatment effeicacy

5. The change in HbA1c from baseline to 12 months and 24 months

Study description

Background summary

Improvements and alternative treatment for diabetic type 2

Study objective

In previous studies, the chronic effect, up to 6 months, of the one gastric lead continuous stimulation was demonstrated resulting in an improvement in blood glucose levels. The present hypothesis is that this effect is mediated by either a reduction of insulin resistance and/ or improvement in the GI hormones levels.

Study design

The study design is a randomized double blind study

Intervention

Gastric pacing with the DIAMOND System

Study burden and risks

See section E

Contacts

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MetaCure Limited

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Male and female subjects 21 through 70 years of age;Body mass index * 28 and * 45 (kg/m2);Type 2 diabetes duration more than 6 months and less than 10 years;A baseline measurement (visit BL1) of HbA1c between * 7.5% and * 10.5%;Type 2 diabetic subjects treated for at least 3 months with one or more maximum tolerable dosage of anti-diabetic-agent, any of the following: Sulfonylurea, Metformin, Thiazolinedione (TZD), DPP-4 inhibitors;Stable anti-hypertensive and lipid-lowering medication for at least one month prior to enrolment, if taken ;Women with childbearing potential (i.e. not postmenopausal or surgically sterilized) must agree to use adequate birth control methods;Ability and willingness to perform required study and data collection procedures and adhere to operating requirements of the System;Alert, mentally competent, and able to understand and willing to comply with the requirements of the clinical trail, and personally motivated to abide by the requirements and restrictions of the clinical trail;Able to provide voluntary informed consent

Exclusion criteria

Injectable anti-diabetic therapy within the last 3 months (such as insulin and/or GLP-1 receptor agonists);Taking medications known to effect gastric motility such as narcotics (chronic use) and anticholinergics/antispasmodics;Any gastric or upper GI surgery;Experiencing severe and progressing diabetic complications (i.e. retinopathy not stabilized, nephropathy with macroalbuminuria;Prior wound healing problems;Diagnosed with past or current psychiatric condition that may impair his of her ability to comply with the study procedures;Use of anti-psychotic medications;Diagnosed with an eating disorder such as bulimia or binge eating ;Obesity due to an endocrinopathy (e.g. Cushing disease, hypothyroidism not treated);Hiatal hernia requiring surgical repair or a paraesophageal hernia;Pregnant or lactating;Diagnosed with impaired liver function (liver enzymes 3 timer greater than normal);Any prior bariatric surgery;Any history of pancreatitis;Any history of peptic ulcer disease within 10 years of enrolment;Diagnosed with gastroparesis or other GI motility disorder;Use of active medical devices (either implantable or external) such as ICD, pacemaker, drug infusion device, or neurostimulator (either implanted or worn). Subjects using an external active device who are able and willing to avoid use of the device during the study may be enrolled;Cardiac history that physician/ surgeon feels should exclude the

subject from the study;Use of another investigational device or agent in the 30 days prior to enrolment;A history of life-threatening disease within 5 years of enrolment ;Any additional condition(s) that in the Investigators opinion would warrant exclusion from the study or prevent the subject form completing the study

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-12-2012
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Diamond system
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	04-06-2012
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL38792.096.12