Continuation of Follow-up for Patients who were Previously Enrolled in the Clinical Study: *Open, Prospective Study to Evaluate the Safety and Preliminary Effectiveness of the BaroSense ACE Stapler for the Treatment of Obesity.*

Published: 06-03-2012
Last updated: 26-04-2024

This study will be performed to evaluate the safety of the ACE stapler for the treatment of obesity. The secondary objective is to evaluate effectiveness of the ACE stapler for the treatment of obesity.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Interventional

Summary

ID

NL-OMON39582

Source
ToetsingOnline

Brief title
Endoscopic plication study

Condition

- Appetite and general nutritional disorders
- Gastrointestinal therapeutic procedures

Synonym
Obesity

Research involving
Human

Sponsors and support

Primary sponsor: Boston Scientific Corporation
Source(s) of monetary or material Support: Boston Scientific Corporation

Intervention

Keyword: ACE stapler, endoscopic, obesity, plication

Outcome measures

Primary outcome

Safety: adverse events, serious adverse events, unexpected adverse events.

Secondary outcome

Effectiveness: weight loss, change in BMI, change in waist circumference,

improvement of co morbidities, improvement in quality of life, diet, excercise

and satiety.

Study description

Background summary

Obesity is a worldwide growing problem. Worldwide more than 300 million people are obese. The number of persons with obesity in the USA has doubled in 30 years. Many of these persons are not helped by diets, behavioural changes or exercise. Surgical procedures that are performed are gastric bypass, laparoscopisch gastric banding and bypass procedures. With this facts in mind, the idea of creating a minimally invasive device to treat patients with obesity. Our previous experience with the Trans-oral endoscopic restrictive device (TERIS) shows safety of the system. However. patency of the system was no longer optimal months after the procedure. The system restrictor was detached in several patients. The system plications were patent throughout the study. For this new study plications will be created in the stomach plications.

Study objective

This study will be performed to evaluate the safety of the ACE stapler for the treatment of obesity. The secondary objective is to evaluate effectiveness of the ACE stapler for the treatment of obesity.

Study design

Prospective, single arm study

Intervention

Patients will be treated with the ACE stapler to form stomach plications to restrict the stomach and to create a feeling of satiety. This endoscopic intervention will be performed during 1-2 hours.

Study burden and risks

Patient burden includes several visits to the outpatient clinic with several a blood tests. Following placement of the anchors a diet has to be followed. During placement of the medical device, risks consist of risks associated with anesthesia, a bleeding, a perforation or infection. Following the procedure a soluble contrast X-ray will be performed to exclude stomach perforations following the procedure. The stomach plications are created using transmural staplers. These may detach after time. These staples will not harm any gastrointestinal tract tissues and leave the body via the faeces.

Contacts

Public
Boston Scientific Corporation

One Boston Scientific Place 1
Natick MA 01760
US
Scientific
Boston Scientific Corporation

One Boston Scientific Place 1
Natick MA 01760
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Subject is willing and able to sign the Informed Consent Form (ICF).
2. Subject was previously enrolled in the *Open, prospective study to evaluate the safety and preliminary effectiveness of the BaroSense ACETM Stapler for the treatment of obesity (11-03)*.

Exclusion criteria

1. Subject is not willing and able to sign the ICF.
2. Subject was not previously enrolled in the *Open, prospective study to evaluate the safety and preliminary effectiveness of the BaroSense ACE Stapler for the treatment of obesity (11-03)*.
3. Subject is taking prescription or over-the-counter weight loss medications during the follow-up period.
4. Subject is taking anticoagulants or other medications which impede coagulation or platelet aggregation.
5. Subject is undergoing steroid or immunosuppressive therapy.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-04-2012
Enrollment:	17
Type:	Actual

Medical products/devices used

Generic name:	Articulating Circular Endoscopic stapler for gastric plications
Registration:	No

Ethics review

Approved WMO Date:	06-03-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-09-2014
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	NL39418.018.12