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Aspiration Therapy for treatment of obesity with AspireAssist™ Aspiration Therapy System

Submission date
28/02/2014

Recruitment status
No longer recruiting

Registration date
13/03/2014

Overall study status
Completed

Last Edited
14/02/2018

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Aspiration therapy is a new method of weight loss for people who are morbidly obese, a serious health condition that can interfere with basic physical functions such as breathing or walking and increases the risk of diseases such as diabetes. This therapy, along with a lifestyle modification program, provides the patient with a method for achieving effective portion control by removing part of their meal from the stomach. This may result in successful weight loss and, along with lifestyle behavior changes, help with long-term weight management. Aspiration therapy was developed by clinicians in the US to provide an alternative to conventional bariatric (weight loss) surgery. The study is intended to investigate the effectiveness of this method of weight loss, the effect of any weight loss on quality of life, whether use of ultrasound during the procedure is helpful, and whether there are any patient groups who benefit more or less from aspiration therapy based on age, gender or initial weight.

Who can participate?
Adult patients 25 65 years of age and with a Body Mass Index (BMI) greater than 35 kg/m2.

What does the study involve?
All participants will undergo an endoscopic procedure to place the tube in the stomach and to create the path from the stomach to the surface of the abdomen. This procedure is very common in patients who require feeding tubes, Percutaneous Endoscopic Gastrostomy (PEG). The procedure is performed under mild sedation and takes about 20 minutes, after which the patient can go home to recover. Once the stoma is healed the tube will be shortened and fitted with a Skin Port. At that time the patient will be taught how to attach the AspireAssist device and how to perform aspiration therapy with the device. This involves several cycles of draining stomach contents into the toilet and then infusion of some water into the stomach. In addition to aspirating three times each day, the patient must participate in lifestyle therapy, which is intended to help the patient change their eating behaviors slowly as they lose weight so that once the weight is lost it is more easily maintained. The patient will also be required to participate in follow-up monitoring to ensure that they remain healthy throughout the weight loss process.

What are the possible benefits and risks of participating?
The benefits of aspiration therapy are weight loss and the known benefits derived from weight loss, the ability of the patient to eat normally and gradually change their behaviors, the procedure is not major surgery and does not change the anatomy of the patient, and finally the procedure is easily and safely reversible should the patient decide that they do not wish to continue or that they no longer need the therapy to maintain their weight. The risks of the endoscopic procedure include abdominal pain, a sore throat, bloating and/or indigestion, and bleeding around the A-Tube site. These problems disappear typically after the first 2-3 days. Occasionally, patients may experience nausea, vomiting, back or shoulder pain due to inflating the abdomen with air for the procedure. Procedure-related infections are addressed by taking antibiotics. Rare risks include pneumonia, infection in the abdomen or intravenous catheter insertion site, infection in the blood, perforation (hole) in the esophagus or stomach, bleeding, or death.
The risks of aspiration therapy (during or immediately after aspiration) include sporadic incidences of indigestion, abdominal discomfort, lightheadedness, irritation of the stomach mucosa (which can cause bleeding). Rare, but potentially serious, risks include severe dehydration and development of abnormal blood electrolyte levels, particularly serum potassium. Close medical monitoring is provided to detect any issues and medications are given should they be needed. Risks of the gastrostomy tube itself include (i) slight discharge around the tube, (ii) scarring or skin indentation at the A-Tube placement site, (iii) (for the first few weeks after the A-tube is inserted) discomfort with bending at the waist and/or sleeping on one s stomach or side, (iv) tube blockages, (v) infection at the A-Tube site, and (vi) leakage of stomach fluid or bleeding around the tube. Regaining significant weight or excessive pulling on the external part of the A-Tube could cause part of the tube inside the stomach to be pulled into the wall of the stomach. If this happens, an endoscopic procedure or a surgical procedure might be needed to remove the entire A-Tube. The A-Tube could accidentally be pulled out of the stomach if it is pulled with force. Placing a new A-Tube will require an additional procedure to place a new A-Tube.

Where is the study run from?
Blekinge Hospital, Karlskrona, Sweden

When is the study starting and how long is it expected to run for?
February 2012 to February 2020.

Who is funding the study?
The study is funded by MINA Medical c/o Meditrust Sweden AB and Aspire Bariatrics, Inc.

Who is the main contact?
Monica Ferrante

Study website
http:// www.aspirebariatrics.com

Contact information

Type(s)
Public

Contact name
Miss Monica Ferrante

Contact details
Aspire Bariatrics Inc.
3200 Horizon Drive, Suite 100
King of Prussia
United States of America
19406

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol number 2012/5

Study information

Scientific Title
Aspiration Therapy for treatment of obesity with AspireAssist™ Aspiration Therapy System: a post-market study

Study objectives
Hypothesis (H0) is that:
1. Aspire Assist™ Aspiration Therapy System gives no weight reduction
2. Quality of life is the same regardless of weight reduction
3. Ultrasound of PEG insertion does not reduce the risk of complications
4. Weight reduction did not differ between different age, gender, ASA class or mass/BMI

Results of US pilot study: http://www.gastrojournal.org/article/S0016-5085(13)01276-6/abstract

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Review Board in Lund (Regionala Etikprovningsnamnden Lund), 22/02/2012

Study design
Single-arm single-site post-market study of an interventional therapeutic device for the treatment of obesity

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information can be found at http://aspirebariatrics.com/what-to-expect/#section-1

Health condition(s) or problem(s) studied
Obesity

Interventions
Added 03/05/207:
The therapy has already been the subject of three pilot studies and is also the subject of a randomized controlled trial in the US under ClinicalTrials.gov NCT01766037 with results published and approved under PMA P150024.

This AspireAssist Aspiration Therapy study is an interventional study without a control. The intervention requires percutaneous endoscopic placement of a tube which is similar to a standard PEG tube, using the pull method. The tube is then used to drain the remaining stomach contents to reduce the caloric intake from the meal. This aspiration process is intended to be performed 20 minutes after each major meal of the day (3x per day) to achieve weight loss. The patient is also required to participate in Lifestyle Therapy. This was implemented as non-RCT study. The device is currently CE Marked and commercially available in the EU.

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Intervention Type
Procedure/Surgery

Primary outcome measure
The dependent variable is: weight reduction
Independent variables are:
1. Diagnosis according to ICD10 for coexisting conditions
2. Voiding frequency
3. Acute phase protein
4. EQ-5D
5. Age, gender, mass/BMI at the start of the study
6. ASA class

Secondary outcome measures
The dependent variable is: quality of life index, as the EQ-5D
Independent variables are: weight gain, age, gender

1. Blood samples: 0, 4, 8, 12, 16, 30, 43 and 56 weeks
2. Urine samples: 0, 16, 30, 43 and 56 weeks
3. Bioelectric Impedance: 0, 16, 30 and 56 weeks

4. Quality of Life, EQ-5D (VAS): 0, 8, 30 and 56 weeks
5. Cognitive Behavioral Therapy (Lifestyle Therapy): Personal (2 sessions) and in Groups (6 sessions)

Overall study start date
01/02/2012

Completion date
01/02/2020

Eligibility

Key inclusion criteria
The AspireAssist Aspiration Therapy System is intended to provide gastric drainage for aspiration therapy to facilitate weight reduction in morbidly obese adults 25 to 65 years with a Body Mass Index (BMI) of >35 kg/m2, and must be used concurrently with a weight management support program.

Patients must have failed to lose weight or maintain long-term weight loss with more conservative weight reduction alternatives, such as diet, exercise and behavior modification programs.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Previous abdominal surgery that significantly increases the medical risks of gastrostomy tube placement
2. Esophageal stricture, pseudo-obstruction, severe gastroparesis or gastric outlet obstruction, inflammatory bowel disease
3. History of refractory gastric ulcers
4. History of radiation therapy to abdomen
5. Uncontrolled hypertension (blood pressure>160/100)
6. Diabetes treated with insulin or sulfonylurea medications
7. Hemoglobin A1C ≥8.5 %
8. History or evidence of serious pulmonary or cardiovascular disease, including acute coronary syndrome, heart failure requiring medications, or NYHA (New York Heart Association) class III or IV heart failure
9. Coagulation disorders (platelets < 100,000, PT > 2 seconds above control or INR > 1.5)
10. Anemia (hemoglobin <11.0 g/dL in women and <12.5 g/dL in men)
11. Pregnant or lactating

12. Physical or mental disability, or psychological illness that could interfere with compliance with the therapy
13. At high risk of having a medical complication from the endoscopic procedure or Aspiration Therapy weight loss program for any reason, including poor general health or severe organ dysfunction such as cirrhosis or renal dysfunction (serum creatinine > 1.5 mg/dL, including Stage II or more severe chronic kidney disease).
14. Diagnosed Bulimia or diagnosed Binge Eating Disorder (using DSM IV criteria)
15. Serum potassium < 3.8 mEq/L.
16. Ulcers, bleeding lesions, or tumors discovered during endoscopic examination
17. Chronic abdominal pain that would potentially complicate the management of the device

Date of first enrolment
01/02/2012

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Czech Republic

Italy

Netherlands

Spain

Sweden

Study participating centre
Kirurgkliniken Blekingesjukhuset
Karlskrona
Sweden
371 85

Study participating centre
Pionyru 690
Pionyru 690
Nehvidzy
PSC 25081
Nehvidzy
Czech Republic
PSC 25081

Study participating centre
Centro Médico Teknon
Unidad de Endoscopia
Vilana 12
Barcelona
Spain
08022

Study participating centre
Rijnstate Ziekenhuis
Rijnstate Ziekenhuis
Wagnerlaan 55
Arnhem
Netherlands
6815 AD

Study participating centre
Ospedale San Raffaelle
Via Olgettina 60
Milan
Italy
20132

Sponsor information

Organisation
MINA Medical (Sweden)

Sponsor details
c/o Medtrust Sweden AB
Schaktugnsgatan 5
LIMHAMN
Sweden
21616

Sponsor type
Industry

Website
http://www.minamedical.se

Funder(s)

Funder type
Industry

Funder Name
MINA Medical (Sweden)

Funder Name
Aspire Bariatrics, Inc.

Results and Publications

Publication and dissemination plan
Not provided at time of registration.

Intention to publish date

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2015		Yes	No
Results article	results	28/12/2016		Yes	No
Results article	results	01/07/2018		Yes	No