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A study to evaluate the safety and efficacy of AspireAssist™ in morbidly obese adolescents

Submission date
19/07/2016

Recruitment status
No longer recruiting

Registration date
03/08/2016

Overall study status
Completed

Last Edited
19/04/2017

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Obesity is a medical term used to describe someone who is very overweight. It is generally caused by eating too much and doing too little exercise. Being obese can lead to a number of serious and potentially life changing conditions including type 2 diabetes, coronary heart disease, some cancers (e.g. breast and bowel cancers) and stroke. It can also affect a person's mental well-being, leading to low self-esteem and depression.Surgery can help people to lose weight. One approach, Aspire Assist ™ (CE approved), comes from the United States and involves the patient emptying some portion of their meal from the stomach. A gastroscopy procedure is used to place a special tube from the stomach through the abdominal wall. Using a valve mechanism and associated drain tube and water reservoir, the patient can empty the stomach contents into a toilet. This should be done about 20 minutes after the meal and this will result in removal of a portion of the calories from the meal. Previous research has shown that the method works in adults and leads to an average of 49 % reduction of excess weight during the course of a year. The aim of this study is to see whether the Aspire Assist ™ system leads to weight loss in younger people who are obese (adolescents) and an improvement in their quality of life.

Who can participate?
Young people aged between 16-21 with a body mass index of 35 to 55 kg/ m2.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 receive the device. Those in group 2 do not receive the device but are treated as usual for their condition. For participants in group 1, a special tube is used to drain the contents of the stomach 20 minutes after a main meal (breakfast, lunch and dinner) is eaten. This is done to reduce the number of calories being absorbed from the meal. All participants are followed up for the next 12 months and are assessed as 3, 6 and 12 months to see how much weight they have lost.

What are the possible benefits and risks of participating?
One major benefit of this treatment (when compared to other surgical treatments for obesity) is that it is completely reversible and if the patient who does not wish to continue the therapy can have the tube removed. It does not alter the anatomy of the stomach in any way. There is a low

risk of mild peritonitis. There is generally post-procedure pain and discomfort from inserting the special tube which resolves quickly and can be treated by pain medication. There may be some nausea and vomiting as a result of sedation and medications. Once under therapy risks are associated with maintaining the stoma site (site where the tube protrudes from the stomach). These include leakage or discharge from the stoma site and some abdominal discomfort. Infrequently there have been fungal infections at the stoma site. All are treatable and seem to be well tolerated by adult patients.

Where is the study run from?
Vítkovice Hospital Surgical Ward (Czech Republic)

When is the study starting and how long is it expected to run for?
September 2016 to March 2019

Who is funding the study?
1. Suppmed, Inc
2. Aspire Bariatrics, Inc

Who is the main contact?
Dr Evžen Machytka

Contact information

Type(s)
Scientific

Contact name
Dr Evžen Machytka

Contact details
Pionyru 690
Nehvidzy
Czech Republic
PSC 25081

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol number 2016/3

Study information

Scientific Title

A study to evaluate the safety and efficacy of AspireAssist™ in morbidly obese adolescents: a randomised controlled trial

Study objectives
1. Aspire Assist ™ System gives no weight reduction
2. Quality of life is the same regardless of weight reduction

Ethics approval required
Old ethics approval format

Ethics approval(s)
Vítkovice Hospital Ethics Committee, 25/06/2015

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: http://www.aspirebariatrics.com/

Health condition(s) or problem(s) studied
Adolescent obesity

Interventions
This AspireAssist study is an interventional study with a control.

The study is designed as a two-arm study with randomization in the proportion of 20 subjects in the treatment group receiving the AspireAssist and 20 subjects in the control group receiving conservative treatment. 20 patients who will undergo implantation of the AspireAssist Device and complete the study protocol in the 12 months following the implantation of the device. Obese adolescents will be enrolled into one of the two arms of the study:

Arm 1: Obese patients with the AspireAssist device
Arm 2: Obese patients treated conservatively

The intervention requires percutaneous endoscopic placement of the A-Tube which is similar to a standard PEG tube, in adolescent subjects with BMI of between 35 and 55 kg/m2. 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 device is currently CE Marked and commercially available in the EU. The therapy has already been the subject of several studies and is also the subject of a randomized controlled trial in adult subjects in the US under ClinicalTrials.gov NCT01766037.

Intervention Type
Device

Primary outcome measure
Body weight reduction measured as % Total Body Weight loss will be evaluated at 3, 6 and 12 months of treatment.

Secondary outcome measures
1. Waist circumference and BMI changes
2. Body composition changes – evaluation of fatty tissue volume reduction
3. Tolerance of the aspiration method by adolescents (to be measured with AspireAssist patient satisfaction survey)
4. Changes in food intake and dietary habits (to be measured with AspireAssist patient satisfaction survey)
5. Quality of life improvement assessed by means of IWQOL and SF-36.

These are all evaluated at 3, 6 and 12 months.

Overall study start date
01/09/2016

Completion date
31/03/2019

Eligibility

Key inclusion criteria
1. Age 16 to 21 years at the time of selection for the study
2. Body mass index (BMI) 35 to 55 kg/ m2
3. Comorbidities such as hypertension and dyslipidemia treated by an appropriate specialist are permissible
4. Ability to comprehend the content of the informed consent form.
5. Cooperation of the subject's parents
6. Non-smoker

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
40

Key exclusion criteria
1. BMI below 35 or above 55
2. History of stomach and gallbladder surgeries
3. Previous technical difficulties with gastroduodenoscopy or a failure to carry out an endoscopy
4. Type 1 diabetes
5. Insulin therapy
6. History of gastrointestinal disease (acute gastritis, non-specific colitis)
7. Confirmed celiac disease
8. History of malignity
9. Previous endoscopic and surgical treatment of obesity (intragastric balloons, endoscopic or surgical gastric procedures, malabsorptive procedures of the GIT)
10. Specific genetic or hormonal disorders associated with obesity (Prader-Wili syndrome, MC4R mutation etc.)
11. Coagulation and hemopoiesis disorders
12. Both chronic and acute pancreatitis
13. Psychiatric disorders (endogenous depression, schizophrenia, suicidal tendencies, psychoses)
14. Uncontrolled hypertension (systolic BP > 150 mm Hg or diastolic BP > 100 mm Hg)
15. Autoimmune diseases or long-term use of systemic glucocorticoids or immunosuppressive therapy
16. Thyroid function disorders unresponsive to treatment
17. Kidney function disorders with GFR < 60 mL/min/1.73 m2 or albumin excretion > 1000 mg/day

Date of first enrolment
01/09/2016

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
Czech Republic

Study participating centre
Vítkovice Hospital Surgical Ward
Zalužanského 1192/15
Ostrava -Vítkovice
Czech Republic
703 84

Sponsor information

Organisation
Vítkovicke Hospital

Sponsor details
Pionyru 690
Nehvidzy
Czech Republic
PSC 25081

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Industry

Funder Name
Suppmed, Inc.

Funder Name
Aspire Bariatrics, Inc

Results and Publications

Publication and dissemination plan
Not provided at time of registration.

Intention to publish date
31/03/2020

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
Not expected to be made available