ISRCTN30159630 https://doi.org/10.1186/ISRCTN30159630

Testing of 8mm A-Tube in AspireAssist™ Aspiration Therapy System

Submission date
30/04/2014

Recruitment status
No longer recruiting

Registration date
22/05/2014

Overall study status
Completed

Last Edited
22/01/2019

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
Obesity is a serious issue in the western world for which there are now a number of treatments including diet, drugs and invasive obesity surgery. An alternative approach, the AspireAssist ™ Aspiration Therapy System (CE-approved), comes from the United States and involves the patient removing a portion of a meal from the stomach before the calories are absorbed into the body, causing weight loss. A specially designed tube is placed into the stomach through the abdominal wall. Using an ingeniously designed valve mechanism and associated drain tube and water reservoir, the patient can empty (aspirate) some of their stomach contents into a toilet. Early results show that the method works; patients lose an average of 49% of their excess weight within a year and without any serious complications. Unlike many other surgical weight loss procedures, this treatment is simple, reversible and does not cause any change in anatomy. The procedure is performed under conscious sedation, takes between 20-30 minutes and patients can normally return home within a couple of hours. The original AspireAssist A-Tube is 6mm in diameter. Here, we are testing whether widening tube diameter to 8mm will result in a reduction in aspiration time and frequency needed to achieve weight loss and whether it will result in less tube blockages.

Who can participate?
Patients that are currently users of the AspireAssist device and have been for at least the last six months.

What does the study involve?
The 6mm tube is replaced with a 8mm tube. The patient then uses the tube to empty a portion of their stomach contents 20 minutes after every major meal.

What are the possible benefits and risks of participating?
The potential benefits include reducing the time taken and the frequency needed for aspiration and also in the number of tube blockages.

Where is the study run from?
Blekinge County Council Hospital (Sweden)

When is the study starting and how long is it expected to run for?
From May 2014 to November 2014

Who is funding the study?
Aspire Bariatrics, Inc (USA)

Who is the main contact?
Dr Monica Ferrante
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Contact information

Type(s)
Scientific

Contact name
Dr - -

Contact details
-
-
Sweden
-

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2014/3

Study information

Scientific Title
Testing of 8mm A-Tube in AspireAssist™ Aspiration Therapy System: a single center / single- arm study

Study objectives
Hypothesis (H0): Aspire Assist ™ Aspiration Therapy System with modified 8mm A-Tube gives the same aspiration time and blockage frequency as the original 6mm A-tube.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Testing Board LUND,18/03/2014, ref. 2014/135

Study design
A single centre single-arm study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
http://aspirebariatrics.com/about-the-aspireassist/

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

Interventions
This AspireAssist Aspiration Therapy study is an interventional study without a control. The intervention requires percutaneous endoscopic replacement of the 6mm A-Tube which is similar to a standard PEG tube, with an 8mm A-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. This is implemented as non-RCT study. The device is currently CE Marked and commercially available in the EU.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. The dependent variable: aspiration time, number of blockages of food at the start of the study and at 7 weeks
2. Independent variables: 6mm A-Tube or 8mm A-Tube, chewing time

Secondary outcome measures
1. The dependent variable: complications (yes/no)
2. Independent variables: 6mm A-Tube or 8mm A-Tube

Overall study start date
15/05/2014

Completion date
15/11/2014

Eligibility

Key inclusion criteria
Patient should currently be a user of the AspireAssist device and have used it for at least six (6) months

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
8

Key exclusion criteria
1. Active infection at the A-Tube
2. Recent (1 month) myocardial infarction
3. The patient is for some reason not considered likely to follow the instructions in the study with respect to diary completion

Date of first enrolment
15/05/2014

Date of final enrolment
15/11/2014

Locations

Countries of recruitment
Sweden

Study participating centre
Kirurgkliniken Blekingesjukhuset
Karlskrona
Sweden
371 85

Sponsor information

Organisation

Aspire Bariatrics, Inc. (USA)

Sponsor details
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Sponsor type
Industry

Website
http://www.aspirebariatrics.com

Funder(s)

Funder type
Industry

Funder Name
Aspire Bariatrics, Inc (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration.

Intention to publish date

Individual participant data (IPD) sharing plan
Do not intend to publish results

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?
Basic results		22/01/2019	22/01/2019	No	No