

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

Submission date 30/04/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/05/2014	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/01/2019	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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
monica.ferrante@aspirebariatrics.com

Contact information

Type(s)
Scientific

Contact name
Dr - -

Contact details
-
-
Sweden
-

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

Funder(s)**Funder type**

Industry

Funder Name

Aspire Bariatrics, Inc (USA)

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes