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Assessing the safety and effectiveness of the BariClip device in the treatment of severe obesity in Jordan

Submission date
29/12/2022

Recruitment status
No longer recruiting

Registration date
16/02/2023

Overall study status
Ongoing

Last Edited
14/02/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Obesity and its associated disorders such as type 2 diabetes, nonalcoholic fatty liver disease, and cardiovascular (heart) disease have reached pandemic proportions worldwide. Conventional medical care offers only limited results, both in weight reduction and associated disorders. Bariatric surgery allows a significant and sustained weight loss in the majority of cases, a decrease in the frequency and severity of associated disorders, including type 2 diabetes, and decreased risk of death including from cardiovascular diseases. However, it requires a major abdominal surgery associated with an estimated 5% significant risk of illness after surgery and an average postoperative risk of death estimated at 0.3%. A new device has been developed which is basically a nonadjustable vertical clip. This device, the BariClip, placed parallel to the lesser curvature of the stomach, aims to restrict food intake without changing the stomach or small bowel anatomy, requires no stapling, causes no malabsorption, does not require any maintenance or surveillance, and is reversible. The aim of this study is to assess the safety and effectiveness of this device as a treatment for obesity and its related disorders.

Who can participate?
Adults between the age of 18 and 65 years with a BMI >40 kg/m² or a BMI >30 kg/m² with at least one associated disorder and a history of obesity for at least 5 years with failed dieting attempts

What does the study involve?
Participants will undergo a laparoscopic clip gastroplasty with the use of the BariClip device and will be followed up for a total of 60 months. Weight loss will be assessed at 1, 3, 6, 12, 18, 24, 36, 48 and 60 months after implantation, and routine labs and imaging will be conducted on day 1, at 3 months, and at 24 months.

What are the possible benefits and risks of participating?
The clip offers a treatment for obesity and its associated disorders that causes fewer complications and is reversible.

Where is the study run from?
Jordan Hospital (Jordan)

When is the study starting and how long is it expected to run for?
December 2022 to June 2028

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Ashraf Haddad, Ashraf.haddad@gbmc-jo.com

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
GBMC 00001

Study information

Scientific Title
Assessing weight loss, adverse events, and resolution of comorbid conditions associated with the use of the BariClip device in adult patients with severe obesity in Jordan

Acronym
BariClip-Jo

Study objectives
The BariClip device provides a reversible alternative to sleeve gastrectomy that is just as efficacious in terms of weight loss.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 31/01/2023, the Institutional Review Boards of Jordan Hospital (Queen Nour Street, PO Box 520248, Amman, Jordan; +962 (0)795528298; jorhos@jordan-hospital.com, saeb.hammoudi@gmail.com), ref: not applicable
2. Approved 11/02/2023, Al Khalidi Hospital & Medical Center (39 Ibn Khaldoun Street, 4th Circle Jebal Amman, Jordan; +962 (0)795598687; Dr.Nael.kaf@khmc.jo), ref: KHMC/22/R/93

Study design
Multicenter prospective single-arm clinical trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Obesity and its associated disorders

Interventions
Laparoscopic vertical clip gastroplasty with the BariClip device.

In the procedure, the clip is placed parallel to lesser curvature to separate the stomach into a restricted medial segment where food passes and an excluded larger lateral gastric segment. It aims to restrict oral intake without changing the gastric or small bowel anatomy, requires no stapling, causes no malabsorption, does not require any maintenance or surveillance, and is reversible.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
BariClip

Primary outcome measure
Percent Excess Weight Loss (%EWL) defined as weight loss divided by baseline excess weight. Excess weight will be determined from ideal body weight based on a BMI of 24.9 for normal adults (Center for Disease Control [CDC]) at 1, 3, 6, 12, 18, 24, 36, 48, and 60 months post-implantation.

Secondary outcome measures
1. Absolute weight loss over 60 months, defined simply as the total weight loss for the follow-up period
2. Total change in weight (TWL%) defined as (preoperative (preop) weight – follow up weight)/ (preop weight) X 100%, measured at 12, 36 and 60 months
3. Total change in BMI (TBMIL%) defined as (preoperative (preop) BMI – follow up BMI)/(preop BMI) X 100%, measured at 12, 36 and 60 months
4. Plasma glucose levels, HbA1c levels, and resolution of T2DM (% of patients, defined as HbA1C<6) in diabetic patients measured annually over 5 years

Overall study start date

01/12/2022

Completion date
30/06/2028

Eligibility

Key inclusion criteria
1. Age 18 – 65 years
2. Male or female
3. BMI >40 kg/m² and BMI >30 kg/m² with at least one comorbid condition (hypertension [HTN], type 2 diabetes [DT2], sleep apnea)
4. Willingness to comply with the substantial lifelong dietary restrictions required by the procedure (written consent form)
5. History of obesity for at least 5 years
6. History of failure with dieting methods
7. Willingness to follow protocol requirements including signed consent, routine follow-up schedule, completing quality of life (QOL) questionnaires, completing laboratory tests, completing diet and behavior modification counseling
8. Residing within a reasonable distance from an investigating center and able to travel to the investigator to complete all routine follow-up visits

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Surgery or treatment represents an unreasonable risk to the subject
2. Patient history of inflammatory disease of the gastrointestinal (GI) tract (including ulceration, duodenal ulceration, grade 4 esophagitis, specific inflammation such as Crohn’s disease or ulcerative colitis)
3. Severe cardiopulmonary disease or other serious organic disease
4. Severe coagulopathy, upper gastrointestinal (UGI) bleeding conditions, such as esophageal or gastric varices, congenital or acquired intestinal telangiectasia
5. Congenital or acquired anomalies of the GI
6. Severe hiatal hernia (>3 cm)

7. Pregnant or has the intention of becoming pregnant in the next 12 months
8. Alcohol or drug addiction, active smoker
9. Mental retardation or emotional instability, or psychological characteristics which, in the opinion of the investigators, make the subject a poor candidate for clip surgery
10. Previous esophageal, gastric surgery, hepatectomy, splenectomy
11. Previous endoscopic procedure for obesity
12. Patient under GLP1 medication or weight loss drug
13. Diabetes patient under treatment for gastroparesis
14. Previous bariatric surgery, intestinal obstruction, or adhesive peritonitis
15. Patient history of a known diagnosis or pre-existing symptoms of systemic lupus erythematosus, scleroderma, or other autoimmune connective tissue disorder
16. Participating in another ongoing clinical trial in which concomitant diagnosis or therapeutic intervention would adversely affect the integrity of the Clip clinical trial

Date of first enrolment
01/03/2023

Date of final enrolment
01/01/2025

Locations

Countries of recruitment
Jordan

Study participating centre
Jordan Hospital
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Study participating centre
Al Khalidi Hospital & Medical Center
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Sponsor information

Organisation
Jordan Hospital

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Sponsor type
Hospital/treatment centre

Website
http://www.jordan-hospital.com/

ROR
https://ror.org/036wxg427

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/12/2026

Individual participant data (IPD) sharing plan
The 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?
Protocol file			13/02/2023	No	No