

High blood pressure after weight loss surgery

Submission date 30/05/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/06/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/05/2023	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Weight loss (bariatric) surgery helps patients quickly and permanently lose weight and recover from other diseases that coexist with obesity, such as high blood pressure (hypertension). The reduction of the size of the stomach (sleeve gastrectomy) and bypassing part of the stomach (one-anastomosis gastric bypass), so food cannot be absorbed, are currently among the most common surgical procedures for overweight patients to achieve significant weight loss. Previous studies have shown that various bariatric surgeries can improve hypertension. Even though bariatric surgery significantly improves or cures hypertension, new studies have documented the return of hypertension after these procedures. To our knowledge, no study has evaluated the return of hypertension between sleeve gastrectomy and one-anastomosis gastric bypass. We examined the number of patients who were previously cured of their hypertension (remission) and then relapsed and assessed the risk factors in hypertensive patients having those surgeries throughout a three-year follow-up period.

Who can participate?

Obese adults with high blood pressure who have had weight loss surgery

What does the study involve?

Obese patients with high blood pressure who had weight loss surgery are followed over time to see if their high blood pressure gets better or returns

What are the possible benefits and risks of participating?

Due to the current study results, a better decision can be made in choosing the type of weight loss surgery for patients with hypertension. Also, according to the patient's condition, controllable factors of hypertension relapse can be identified, and action can be taken to prevent it

Where is the study run from?

Tehran Obesity Treatment Center

When is the study starting and how long is it expected to run for?

January 2013 to March 2022

Who is funding the study?
Research Institute for Endocrine Sciences (Iran)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Comparison of hypertension remission and relapse after sleeve gastrectomy and one-anastomosis gastric bypass

Study objectives

The rate of remission and relapse of hypertension varies between sleeve gastrectomy and one-anastomosis gastric bypass

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 07/12/2021, Research Ethics Committee of the Research Institute for Endocrine Sciences of Shahid Beheshti University of Medical Sciences (Yaman Street, Velenjak, Tehran, 1985717434, Iran; +98 22439951; mpd@sbmu.ac.ir), ref. IR.SBMU.ENDOCRINE.REC.1400.096.

Study design

Observational prospective cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Hypertension

Interventions

A prospective cohort study with a follow-up of three years was conducted on severely obese patients between 2013 and 2018 in the context of Tehran Obesity Treatment Study who

underwent sleeve gastrectomy or one-anastomosis gastric bypass. Hypertension (HTN) remission was defined as the normalization of blood pressure (BP) with the discontinuation of medical treatment, and HTN relapse was defined as the need for the onset of antihypertensive drugs or the occurrence of BP impairment.

Intervention Type

Procedure/Surgery

Primary outcome measure

1. Hypertension (HTN) remission, as defined in established guidelines, measured using a mercury sphygmomanometer twice on the left arm for a minimum of 30 seconds while the patient was seated on a chair and using the Korotkoff sound technique at pre-surgery, 3-, 6-, 12-, 18-, 24-, and 36-months post-surgery.

HTN was defined as systolic blood pressure (SBP) equal to or above 140 mm Hg or diastolic blood pressure (DBP) equal to or above 90 mm Hg. In patients with preoperative HTN, remission was identified on the day on which the patient met all of the following three criteria:

- 1.1. SBP <140 mm Hg
- 1.2. DBP <90 mm Hg
- 1.3. Discontinuation of antihypertensive drugs

2. HTN relapse, which due to the lack of a clear definition was defined as the deterioration of HTN remission, measured using a mercury sphygmomanometer twice on the left arm for a minimum of 30 seconds while the patient was seated on a chair and using the Korotkoff sound technique at pre-surgery, 3-, 6-, 12-, 18-, 24-, and 36-months post-surgery.

Relapse in the patients who experienced remission after bariatric surgery was defined as follows:

- 2.1. The need for prescribing any antihypertensive drug regardless of BP
- 2.2. SBP \geq 140 mm Hg or DBP \geq 90 mm Hg

3. Biochemical parameters in blood samples collected between 7 and 9 am after 12 to 14 hours of overnight fasting were measured on the same day:

- 3.1. Fasting plasma glucose, as measured using the enzymatic colorimetric method at pre-surgery, 3-, 6-, 12-, 18-, 24-, and 36-months post-surgery
- 3.2. Serum triglyceride, as measured using the enzymatic colorimetric method at pre-surgery, 3-, 6-, 12-, 18-, 24-, and 36-months post-surgery
- 3.3. Total cholesterol, as measured using the enzymatic colorimetric method at pre-surgery, 3-, 6-, 12-, 18-, 24-, and 36-months post-surgery
- 3.4. High-density lipoprotein-cholesterol, as measured after precipitation of apolipoprotein B-containing lipoproteins with phosphotungstic acid at pre-surgery, 3-, 6-, 12-, 18-, 24-, and 36-months post-surgery
- 3.5. Low-density lipoprotein-cholesterol, as measured using serum total cholesterol, triglyceride, and high-density lipoprotein-cholesterol concentrations at pre-surgery, 3-, 6-, 12-, 18-, 24-, and 36-months post-surgery. (Friedewald formula: LDL cholesterol = total cholesterol - HDL - (triglycerides / 5))
- 3.6. Hemoglobin A1C, as measured using affinity chromatographic method at pre-surgery, 3-, 6-, 12-, 18-, 24-, and 36-months post-surgery

Secondary outcome measures

The relationship between remission and relapse of HTN was measured using a Cox regression analysis of risk factors such as:

1. Smoking measured using a questionnaire (never, past, current smoker) at baseline
2. Diabetes as defined as fasting plasma glucose \geq 126 mg/dl or hemoglobin A1C \geq 6.5 or current

medication therapy for a definite diagnosis of diabetes at baseline

3. Lack of appropriate weight loss after surgery measured using EWL < 70% at one year after surgery ($\text{EWL\%} = \frac{[\text{Initial weight} - \text{Postop weight}]}{[\text{Initial weight} - \text{Ideal weight}]} * 100$)

4. Old age measured using a questionnaire (more than 45 years) at baseline

5. High consumption of antihypertensive drugs was measured using a questionnaire (more than two antihypertensive drugs) at baseline

Overall study start date

01/01/2013

Completion date

28/03/2022

Eligibility

Key inclusion criteria

1. Enrollment in the TOTS study with a body mass index >35
2. Participants aged 18 years and over
3. Preoperative hypertension
4. Bariatric surgery consisting of sleeve gastrectomy or one-anastomosis gastric bypass

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

4320

Total final enrolment

787

Key exclusion criteria

1. Secondary hypertension (secondary to renal sclerosis, primary hyperaldosteronism, conns syndrome, renovascular problems)
2. Chronic kidney disease with eGFR < 60
3. Current Cancer
4. Revisional bariatric surgery

Date of first enrolment

31/03/2013

Date of final enrolment

31/05/2018

Locations

Countries of recruitment

Iran

Study participating centre

Tehran Obesity Treatment Center

Tehran

Iran

1985717413

Study participating centre

Mostafa Khomeini Hospital

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Study participating centre

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Study participating centre

Khatam-Al-Anbya Hospital

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Tehran Province

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Sponsor information

Organisation

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Sponsor type

Research organisation

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Funder(s)**Funder type**

University/education

Funder Name

Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences

Alternative Name(s)

Research Institute for Endocrine Sciences, RIES

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Iran

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

30/11/2022

Individual participant data (IPD) sharing plan

The datasets used and analyzed in the current study are available from the corresponding author Dr Maryam Barzin m.barzin7@gmail.com on reasonable request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/01/2023	23/05/2023	Yes	No