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High blood pressure after weight loss surgery

Submission date	Recruitment status	[_] Prospectively registered
30/05/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/06/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/05/2023	Circulatory System	

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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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.

Primary study design
Observational

Study design
Observational prospective cohort study

Study type(s)
Treatment

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(s)
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 ≥ 140 mm Hg or DBP ≥ 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 measure 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

Key secondary outcome(s)
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 ≥ 126 mg/dl or hemoglobin A1C ≥ 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 tear after surgery (EWL% = [Initial weight - Postop weight] / [Initial weight - 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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
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Study participating centre
Mostafa Khomeini Hospital
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Study participating centre
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Sponsor information

Organisation
Research Institute for Endocrine Sciences

ROR
https://ror.org/01kpm1136

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

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