

BYM [Bypass and Sleeve gastrectomy (Bypass y Manga)]: Mineral absorption and mineral nutritional status in patients with severe and morbid obesity - effects of gastric bypass and sleeve gastrectomy

Submission date 26/06/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/08/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 09/04/2021	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Weight loss surgery (also called bariatric surgery) is the method that currently works best to induce sustained weight loss in severe and morbid obese individuals. Roux-en-Y gastric bypass (RYGBP) and sleeve gastrectomy (SG) are among the most commonly used techniques. RYGBP is a restrictive and malabsorptive technique (malabsorption means that the body does not absorb certain nutrients), whereas SG is a restricted only approach. Knowledge regarding the effects of bariatric surgery on absorption and metabolism of minerals, as well as cellular and molecular mechanisms involved is limited. This research aims to study the mechanisms through which Roux-en-Y gastric bypass and sleeve gastrectomy affect absorption, metabolism and the nutritional status of selected minerals.

Who can participate?

Subjects will be recruited among women with residence in Santiago, Chile, starting in March 2008.

What does the study involve?

The study will be carried out in adult pre menopausal women with body mass index (BMI) > 35 kg/m² plus some co-morbidities such as hypertension, diabetes, insulin resistance, sleep apnea, dyslipidemia or BMR > 40 kg/m² regardless the presence of co-morbidities, using a contraceptive method (IUD, oral contraceptives or tubal ligation). Patients will be evaluated from the period immediately before, until 12 and 24 months after the surgery. The patient's doctor will decide whether the patient is treated by RYGBP or SG. Before and after 12 and 24 months of RYGBP and SG, Zn, heme iron, non-hem iron, and calcium absorptions will be evaluated, besides, a series of determinations related to nutritional status of Zn, Fe, Cu and Ca will be carried out. Other determinations include body composition, bone mineral density, and plasma hormones such as adiponectin and ghrelin. Before and after 12 months of surgery gene expression of mineral-

related cell transporters will be determined in intestinal mucosa and peripheral mononuclear cells.

What are the possible benefits and risks of participating?

Benefits include the results of a comprehensive description of patients' Zn, Fe, Ca, and Cu nutritional status during the first two years after surgery, which may be useful for further adjustment of their nutritional management. Risks involve the potential inconveniences related to surgical procedures, all of them explained in detail in the informed consent form.

Where is the study run from?

All procedures on the patients will be carried out at the Department of Nutrition, Faculty of Medicine, University of Chile, Santiago, Chile.

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

The study started in March 2008 and is expected to be completed in November 2012.

Who is funding the study?

The study is funded by the National Fund for the Development of Science and Technology (Fondecyt), Chile.

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Fondecyt 1080576

Study information

Scientific Title

Studies of the effects of Roux-en-Y gastric bypass and sleeve gastrectomy in morbid obesity on mineral and absorption and metabolism: cellular mechanisms involved

Acronym

BYM

Study objectives

1. Roux-en-Y gastric bypass (RYGBP) will have a greater effect on iron (Fe), zinc (Zn), copper (Cu) and calcium (Ca) nutritional status than sleeve gastrectomy (SG). In both types of surgery the effects will be more profound after 12 than 24 months of the intervention.
2. The intestinal absorption of zinc, calcium, heme iron, and non-heme iron will be decreased after RYGBP and SG. Such impairment will be more important after RYGBP than after SG and in both cases decreased absorption will be greater after 12 than 24 months of surgery.
3. Twelve months after SG, gene expression of Zn, Fe, Cu and Ca transporters will be increased in duodenal mucosa with respect to pre surgery values.
4. Twelve months after RYGBP gene expression of Zn, Fe, Cu and Ca transporters in jejunum mucosa close to the stomach will tend to mimic gene expression of transporters observed in duodenal mucosa.
5. Twelve and 24 months after RYGBP and SG bone mineral density will be decreased compared to pre surgery values. This change will be related to increased adiponectin and decreased ghrelin plasma concentrations and it will be independent of calcium intake and absorption.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Ethics Committee for Research in Humans from the Faculty of Medicine of the University of Chile, 12/07/2007, ref: 1296
2. Advisor Ethics committee of the Granting Agency (Fondecyt), 18/03/2008

Study design

Interventional non-randomized parallel two arms

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 below to request a patient information sheet

Health condition(s) or problem(s) studied

Severe and morbid obesity

Interventions

The decision in terms of what type of surgical procedure the patient will undergo (Roux-en-Y gastric bypass or sleeve gastrectomy) is made by the patient's surgeon. After the surgery the individuals receive two types of supplements as detailed later; because RYGBP is a restrictive-malabsorptive procedure amounts of micronutrients is greater than that of sleeve gastrectomy.

1. RYGBP group: A vitamin-mineral supplement (Maltofer vit® Andromaco Laboratories, Santiago, Chile (1 tablet/d) + a Calcium and vitamin D supplement (Elcal D-PLUS® Andromaco Laboratories, Santiago, Chile) (1 tablet/d).
2. SG group: A vitamin-mineral supplement (Centrum® Wyeth laboratories, St Laurent, Montreal, Canada) (1 tablet/d) + a specially designed mineral capsule containing 22 mg Fe, 8.5 mg Zn, and Cu 1.1 mg (1 capsule/d) + a Calcium and vitamin D supplement (Elcal D-PLUS® (1 tab/d).

The composition of each supplement is shown in the following table

Daily supply of selected micronutrients provided to obese women after Sleeve gastrectomy (SG) and Roux-en-Y gastric bypass (RYGB)

SG - RYGBP

Calcium (mg) 662 - 750

Mg mg 100 - 30

Zinc (mg) 15 - 25

Iron (mg) 36 - 60

Copper (ug) 1800 - 3000

Selenium (ug) 25 - 0

Manganese (mg) 2.5 - 5

Iodine (ug) 150 -200

Chromium (ug) 25 - 50

Molibdenum (ug) 25 - 50

Beta carotene (mg) 600 - 0

Vitamin C (mg) 60 -100

Vitamin E (mg) 15 - 30

Folic acid (ug) 200 -1000

Thiamin (mg) 1.4 - 3

Riboflavin (mg) 1.6 - 3

Vitamin B6 (mg) 2 -10

Vitamin B12 (ug) 1 -10

Niacin (mg) 18 - 30

Biotin (ug) 150 - 100

Panthotenic acid (mg) 6 -7

Vitamin A (ug) 600 - 1200

Vitamin D (IU) 600 - 800

Intervention Type

Procedure/Surgery

Primary outcome measure

1. Zn and Ca determined by the use of stable isotopes
2. Hem Fe and non-hem Fe absorption determined by the use of radioactive isotopes
3. Zn status (Plasma Zn, hair Zn, rapidly exchangeable zinc pool EZP)
4. Ca status (PTH, serum Ca and vitamin D)
5. Fe status (Hemoglobin, hematocrit, zinc-protoporphyrin, serum ferritin, serum transferrin receptor and
6. Cu status (plasma Cu)

Measured before and 12 and 24 months after surgery

Secondary outcome measures

1. Hormone (ghrelin and adiponectine concentrations) measured before and 12 and 24 months after surgery
2. Body composition and bone mineral density (by DEXA) measured before and 12 and 24 months after surgery
3. Mieral-related gene expression (Ca: TRPV5 and TRPV6; Fe: DMT1 and FPN1; Zn: Zip 4 and ZnT1; Cu: hCTR1 and ATP7A) intestinal biopsies before and 12 months after surgery

Overall study start date

18/03/2008

Completion date

30/11/2012

Eligibility

Key inclusion criteria

1. Adult pre-menopausal women with body mass index (BMI) > 35 plus some co-morbidities such as hypertension, diabetes, insulin resistance, sleep apnea, dyslipidemia or BMR > 40 regardless the presence of co-morbidities
2. Indication of Roux-en-Y gastric bypass or sleeve gastrectomy
3. The use of a contraceptive method (IUD, oral contraceptives or tubal ligation), will be required prior to participation in the studies due to the use of radioactive isotopes. Furthermore, a pregnancy test will be conducted before the study
4. Consent to participate

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

40

Key exclusion criteria

1. Record of inflammatory bowel disease
2. Malabsorption syndrome
3. Liver or pancreatic disease
4. Chronic anemia
5. Low adherence to previous medical treatments
6. Pregnancy

Date of first enrolment

18/03/2008

Date of final enrolment

30/11/2012

Locations

Countries of recruitment

Chile

Study participating centre

University of Chile

Santiago

Chile

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Sponsor information

Organisation

University of Chile (UK)

Sponsor details

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Sponsor type

University/education

Website

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ROR

Funder(s)

Funder type

Government

Funder Name

Fondo Nacional de Desarrollo Científico y Tecnológico

Alternative Name(s)

National Fund for Scientific and Technological Development, El Fondo Nacional de Desarrollo Científico y Tecnológico, FONDECYT

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Chile

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2012		Yes	No
Results article	results	01/06/2014		Yes	No
Results article	results	01/07/2018		Yes	No
Results article		01/07/2021	09/04/2021	Yes	No