Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of nutritional counselling among post-op Mini-gastric Bypass patients in terms of Quality of life.

Protocol summary

Study aim
The aim of this study is to compare improvement in Quality of life after nutritional counselling among post-op MGB patients.

Design
Prospective comparative study

Settings and conduct
The study will be conducted in General Surgery Department, Ammar Medical complex Lahore, Pakistan.

Participants/Inclusion and exclusion criteria
Inclusion criteria • Patients with either gender with age group ranging between 18 to 60 years. • Patients with bariatric surgery which was not older than 6 months. • Patients with no fracture or limbs issue. • No previous bariatric surgical history • No coexisting diseases affecting the function of the limbs. Exclusion criteria • Patients below 18 and above 60 years of age. • Patients with bariatric surgery more than 6 months. • Patients with fractures of limbs. • Pregnant ladies after a bariatric surgery were not a part of it. • Patients who were suffering from depression and taking anti-depressant medication. • Patients who refuse our protocol.

Intervention groups
Any difference in results between the groups has the potential to enhance current practice and patient life significantly. The purpose of this study is to contribute to the literature by comparing nutritional counselling. In nutritional counselling group, better results with the MGB will encourage the demand of this minimally invasive counselling.

Main outcome variables
Any difference in results between the groups has the potential to enhance current practice and patient life significantly. The purpose of this study is to contribute to the literature by comparing nutritional counselling. In nutritional counselling group, better results with the MGB will encourage the demand of this minimally invasive counselling

General information

Reason for update

Acronym
NCT

IRCT registration information
IRCT registration number: **IRCT20240415061496N1**
Registration date: **2024-05-18, 1403/02/29**
Registration timing: **registered_while_recruiting**

Last update: **2024-05-18, 1403/02/29**
Update count: **0**

Registration date
2024-05-18, 1403/02/29

Registrant information

Name
Dr amna amar butt

Name of organization / entity
Ammar medical complex

Country
Pakistan

Phone
+92 335 4614376

Email address
amaramarbutt123@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-05-04, 1403/02/15

Expected recruitment end date
2024-10-04, 1403/07/13

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of nutritional counselling among post-op Mini-gastric Bypass patients in terms of Quality of life.

Public title
Effectiveness of nutritional counselling among post-op Mini-gastric Bypass patients in terms of Quality of life.

Purpose
Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:
• Patients with either gender with age group ranging between 18 to 60 years.• Patients with bariatric surgery which was not older than 6 months. • Patients with no fracture or limbs issue.• No previous bariatric surgical history • No coexisting diseases affecting the function of the limbs.

Exclusion criteria:
• Patients below 18 and above 60 years of age.• Patients with bariatric surgery more than 6 months. • Patients with fractures of limbs.• Pregnant ladies after a bariatric surgery were not a part of it.• Patients who were suffering from depression and taking anti-depressant medication.• Patients who refuse our protocol.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple random sampling using lottery method.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ammar medical complex etjcal committee

Street address
Ammar Medical Complex, Lahore

City
lahore

Postal code
54000

Approval date
2024-05-07, 1403/02/18

Ethics committee reference number
1004

Health conditions studied

1

Description of health condition studied
bariatric surgery post op patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
. The purpose of this study is to contribute to the literature by comparing nutrtitional counselling.

Timepoint
4 months after surgery

Method of measurement
The clinical proforma (annexure-I) will collect data, fed into, assessed, and analyzed using the SPSS software version 22. Quantitative data will be described as means and standard deviations. Percentages and frequencies would be determined for qualitative data. Linear regression analysis will be performed to determine correlation of age, gender and clinical outcome

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
The study will be conducted in General Surgery Department, Ammar Medical complex Lahore.

Full name of responsible person
dr amna amar butt

Street address
G8MV+X55 Ammar Medical Complex:, Jail Rd, Gulberg V, Lahore, Punjab

City

lahore
Postal code
54000
Phone
+92 335 4614376
Email
amaramarbutt123@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
ammar medical complex
Full name of responsible person
dr maaz ul hassan
Street address
110,A,C-2, johar town lahore
City
lahore
Postal code
54782
Phone
+92 335 4614376
Email
amaramarbutt123@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
ammar medical complex
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
ammar medical complex
Full name of responsible person
dr amna amar butt
Position
bariatric dietitian
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
122,A,C-2, johar town lahore
City
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Person responsible for scientific inquiries

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Full name of responsible person
prof dr maaz ul hassan
Position
general surgeon
Latest degree
Specialist
Other areas of specialty/work
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punjab
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Phone
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Email
drmaaz@hotmail.com

Person responsible for updating data

Contact
Name of organization / entity
ammar medical complex
Full name of responsible person
dr amna amar butt
Position
bariatric dietitian
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
122,A,C-2, johar town lahore
City
lahore
Province
punjab
Postal code
54782
Phone
+92 335 4614376
Email
dramnaamarbutt@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Effectiveness Of Nutritional Counselling Among Post-Op Mini Gastric Bypass Patients In Terms Of Quality Of Life
This study was a six-month randomized control trial conducted in the General Surgery Department at Ammar Medical Complex Lahore. The study included 145 eligible participants who had undergone bariatric surgery within six months and had no prior bariatric surgery, fractures, limb issues, or coexisting diseases affecting limb function. The participants were randomly divided into two groups, one receiving nutritional counseling and the other not. The data were analyzed using SPSS software version 22, and descriptive statistics were calculated

When the data will become available and for how long
after 4 months

To whom data/document is available
to dr amna amar butt

Under which criteria data/document could be used
for publication purpose only

From where data/document is obtainable
from hospital

What processes are involved for a request to access data/document
application form

Comments