Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of the Effectiveness of Kefir and Yogurt on Antropometric and Metabolic Parameters, Vaspin, Metabolic Endotoxemia and Appetite in Patients undertake Bariatric Surgery and follow up of Weight Change, Body Shape Conception, Food Intake and Appetite in Patients after Completing the Intervention Phase

Protocol summary

Study aim
Comparison of the effects of kefir and yogurt on anthropometric parameters, body composition, appetite, lipid profile and blood glucose, serum levels of vaspin and lipopolysaccharide in obese patients undergoing bariatric surgery

Design
This study is a clinical trial with a control group in parallel design and single blind. In each group, 24 patients undergoing bariatric surgery enter the study from day 14 after surgery and consume 100 g of yogurt or kefir daily for 8 weeks. In addition to completing the 8-week intervention phase, all patients will be rechecked for some parameters in the 16th week after surgery.

Settings and conduct
In this clinical trial study, patients admitted to Ghadir Shiraz Maternal and Child Hospital for bariatric surgery were evaluated for inclusion criteria and enter the study by completing a written consent. Patients will receive 100 grams of yogurt or kefir daily for 8 weeks from day 14 after surgery. At the end, blood sampling, questionnaires, anthropometric measurements, blood pressure, and body composition will be performed. At week 16 after surgery, patients will be assessed for weight, body composition and appetite. Only patients do not know if they receive yogurt or kefir (single blind).

Participants/Inclusion and exclusion criteria
age 20 to 60 years, BMI greater than 40 or more than 35 with comorbidity disease, patient undergoing bariatric surgery; Chronic gastrointestinal and liver disease, Get antibiotics, nosocomial infections, hospitalization for more than 10 days, consumption of probiotic supplements in the past month

Intervention groups
In this study, the intervention group will receive kefir and the control group will receive yogurt as placebo for maximum similarity.

Main outcome variables
Anthropometric parameters; Body composition; Appetite; Lipid profile; Insulin and FBS; vaspin; Serum lipopolysaccharide

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190531043776N1**
Registration date: **2019-10-13, 1398/07/21**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-13, 1398/07/21**
Update count: **0**

Registration date
2019-10-13, 1398/07/21

Registrant information

Name
Reyhane Basirat
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-06, 1398/06/15
Expected recruitment end date
2019-11-21, 1398/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Kefir and Yogurt on Antropometric and Metabolic Parameters, Vaspin, Metabolic Endotoxemia and Appetite in Patients undertake Bariatric Surgery and follow up of Weight Change, Body Shape Conception, Food Intake and Appetite in Patients after Completing the Intervention Phase

Public title
Effect of kefir after bariatric surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
BMI more than 40 or more than 35 with comorbidity diseases Patients undergoing bariatric surgery
Exclusion criteria:
More than 10 days after surgery Chronic gastrointestinal diseases and liver Gastrointestinal infection after surgery and receiving antibiotics Long-term hospitalization after surgery (more than 10 days)
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients included in this study will be unaware that they are in the yogurt recipient group or in the kefir recipient group. On the other hand, due to the similarity of appearance of both products in the packages of similar appearance and with the same label given to the participants, it has been tried to blind the patients. But other people involved in the process know how to classify intervention and control groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
School of Nutrition and Food Sciences, Razi Blvd, Shiraz
City
Shiraz
Province
Fars
Postal code
7153675541
Approval date
2018-12-25, 1397/10/04
Ethics committee reference number
IR.SUMS.REC.1397.970

Health conditions studied

1

Description of health condition studied
Bariatric surgery, gastric bypass surgery
ICD-10 code
E66.01
ICD-10 code description
Morbid (severe) obesity due to excess calories

Primary outcomes

1

Description
weight loss
Timepoint
At baseline, 4, 8, and 16 weeks after intervention
Method of measurement
Digital Scale

2

Description
Body composition
Timepoint
At baseline and 8 and 16 weeks after the intervention
Method of measurement
body composition measuring device Inbody

Secondary outcomes

1

Description
vaspin
Timepoint
At baseline and And 8 weeks after intervention
Method of measurement
Serum level by Kit ELISA

2

Description
Lipopolysaccharide
Timepoint
At baseline and And 8 weeks after intervention
Method of measurement
Serum level by Kit ELISA

Intervention groups

1

Description
Intervention group: Patients in the intervention group, 14 days after surgery, will receive 100 grams of low-fat kefir pasteurized yogurt daily for 8 weeks daily, in addition to dietary recommendations and specific dietary plans. The yogurt will be distributed to patients every two weeks. Kefir yogurt will be purchased from the Kalleh Dairy Co. (PJS.), which is classified into probiotic products, and in addition to the beneficial bacteria contained the Saccharomyces cervisae yeast .
Category
Treatment - Other

2

Description
Control group: Patients in the control group received 100 grams of pasteurized yogurt daily, in addition to dietary recommendations and diet similar to the intervention group, on the 15th day after surgery for 8 weeks. The yogurt will be distributed to patients every two weeks and the calorie intake of kefir yogurt will be balanced against yogurt. This yogurt will also be purchased from the Kalleh Dairy Co. (PJS.), the main difference between the control and the intervention being the kefir starter in the intervention group, in other word, the control group will consume only fermented product but the intervention group will receive a fermented starter-based probiotic product.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz Ghadir Mother and child hospital
Full name of responsible person
Dr.Masoud Amini
Street address
Ghadir Mother And Child Hospital, Gloshan Town, Shiraz, Iran
City
shiraz
Province
Fars
Postal code
7144995377
Phone
+98 71 3227 9701
Email
motherhosp@gmail.com
Web page address
http://shirazmch.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Younes Ghasemi
Street address
Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran
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Phone
+98 71 3235 7282
Email
vcrdep@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Reyhane Basirat

Position
phd candidate

Latest degree
Master

Other areas of specialty/work
Nutrition

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Not applicable

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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Informed Consent Form and Clinical Study Report; The informed consent form, based on the frameworks of the research deputy of Shiraz University of Medical Sciences, will be completed by patients before the intervention begins. Clinical study report: Information that is relevant to the main outcome of the study will be shared after non-identifiable information is shared.

When the data will become available and for how long
Start of access period 8 months after publication of results.

To whom data/document is available
Everyone is allowed to submit a request.

Under which criteria data/document could be used
Depending on the circumstances, the time will be decided.

From where data/document is obtainable
basirat@sums.ac.ir

What processes are involved for a request to access data/document
If the submitted request is responsive after consultation

with the research team, the applicant receives the requested documentation within a one-month period.

Comments