

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of the Effectiveness of Kefir and Yogurt on Anthropometric 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)

Phone

+98 71 3725 8099

Email address

basirat@sums.ac.ir

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 Anthropometric 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)

AgeFrom **20 years** old to **60 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant

Sample sizeTarget 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 cerevisiae* 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, Glosan 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

City

shiraz

Province

Fars

Postal code

۷۱۳۴۸۱۴۳۳۶

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

Street address

School of Nutrition and Food Sciences, Razi s.t,
Shiraz, Iran.

City

Shiraz

Province

Fars

Postal code

7153675541

Phone

+98 71 3725 1001

Email

r.basirat@yahoo.com

Person responsible for scientific 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

Street address

School of Nutrition and Food Sciences, Razi Blvd,
Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7153675541

Phone

+98 71 3725 8099

Fax**Email**

basirat@sums.ac.ir

Person responsible for updating data

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

Street address

School of Nutrition and Food Sciences, Razi s.t,
Shiraz, Iran.

City

Shiraz

Province

Fars

Postal code

7153675541

Phone

+98 71 3725 1001

Email

r.basirat@yahoo.com

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