

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Ketogenic diet on patients with locally advanced and metastatic breast cancer

Protocol summary

Study aim

Determination of Complete Response Rate in intervention group and control group
Determination of tumor volume in intervention group and control group
Determination of pathological, biological features of tumor in intervention group and control group
Determination of IGF1 and Insulin level in intervention group and control group
Determination of glucose level in intervention group and control group
Determination of serum ketone level in intervention group and control group
Determination of quality of life in intervention group and control group

Design

randomised controlled trial

Settings and conduct

We plan to recruit 60 patients with locally advanced and metastatic breast cancer from Shohada-Tajrish hospital in Tehran, Iran

Participants/Inclusion and exclusion criteria

Inclusion criteria: patient with neoadjuvant and metastatic breast cancer that will undergo chemotherapy for at least 3 months patient accept follow ketogenic diet for 3 months. Karnofsky index $>=70$ \square $18 \text{ kg/m}^2 < \text{BMI} < 34.5 \text{ kg/m}^2$ \square Age between 18 and 75 years
exclusion criteria: Type I diabetes \square Pregnancy \square Known defects in enzymes necessary for ketogenesis, ketolysis, fatty acid oxidation or gluconeogenesis patient with cardiac or liver or kidney disease

Intervention groups

ketogenic diet will be prescribed for 3 month in intervention group. ketogenic diet contain (5-10% CHO, 15-20% Protein, 70 -80% FAT based on 20% MCT from nutricia company). Standard diet will be prescribed for control group. Standard diet contain 55% CHO, 30% FAT and 15% protein.

Main outcome variables

Complete Response Rate IGF1 and Insulin level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171105037259N2**

Registration date: **2018-05-21, 1397/02/31**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-21, 1397/02/31**

Update count: **0**

Registration date

2018-05-21, 1397/02/31

Registrant information

Name

Adeleh Khodabakhshi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 910 667 3806

Email address

khodabakhshiadeleh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-26, 1397/02/06

Expected recruitment end date

2018-10-22, 1397/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Ketogenic diet on patients with locally advanced and metastatic breast cancer

Public title

Effect of ketogenic diet on patients with breast cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with locally advanced and metastatic breast cancer (Stage III or IV) that will undergo chemotherapy for at least 3 months; Patients who accept ketogenic diet for 3 months; Between 18 -75 years old; BMI between 18.5 - 35.5; Karnofsky Performance Score more than 70%

Exclusion criteria:

Type I diabetes under Insulin therapy; Patients with liver, kidney or cardiac disease; Congenital metabolic disorders that impair Ketogenic diet such as Gluconeogenesis defect; Pregnancy

Age

From **18 years** old to **75 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Balanced Randomization will be used.

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

Ethics committee Shahid Beheshti University of Medical SCIENCE

Street address

•No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2018-03-14, 1396/12/23

Ethics committee reference number

IR.SBMU.nnftri.Rec.1396.187

Health conditions studied

1

Description of health condition studied

breast cancer

ICD-10 code

C50.91

ICD-10 code description

Malignant neoplasm of breast of unspecified site, female

Primary outcomes

1

Description

Complete response rate

Timepoint

At the baseline and the end of the study

Method of measurement

clinical exam,lab test and imaging

Secondary outcomes

1

Description

Insulin level

Timepoint

0, 45, 90

Method of measurement

Eliza

Intervention groups

1

Description

Intervention group: ketogenic diet. ketogenic diet contain (5-10% CHO,15-20% Protein, 70 -80% FAT based on 20% MCT from nutricia company).

Category

N/A

2

Description

Control group: Standard diet. Standard diet contain 55% CHO, 30% FAT and 15% protein.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Research center -Shohada-e-Tajrish Hospital

Full name of responsible person

Adeleh khodabakhshi

Street address

Shahrdari Ave,Tajrish Square,Shohada Tajrish Hospital

City

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1989934148

Phone

+98 21 2274 8001

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khodabakhshiadeleh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Deputy of Research and Technology

Street address

Velenjak Ave.Shahid Beheshti University of Medical Science

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Postal code

1985717443

Phone

+98 21 23871

Email

info@sbmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Adeleh Khodabakhshi

Position

PhD candidate

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

PhD candidate

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Adeleh Khodabakhshi

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Phone

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Email

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

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

make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

result of study

When the data will become available and for how long

2018

To whom data/document is available

all of them

Under which criteria data/document could be used

khodabakhshiadeleh@yahoo.com

From where data/document is obtainable

khodabakhshiadeleh@yahoo.com

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

khodabakhshiadeleh@yahoo.com

Comments