

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 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  $\geq 70$   $\square$  18 kg/m<sup>2</sup> < BMI < 34.5 kg/m<sup>2</sup>  $\square$  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**

tehran

**Province**

Tehran

**Postal code**

1989934148

**Phone**

+98 21 2274 8001

**Email**

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

**City**

Tehran

**Province**

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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**

Adeleh Khodabakhshi

**Position**

PhD candidate

**Latest degree**

Ph.D.

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## Person responsible for updating data

#### Contact

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Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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**City**

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**Province**

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**Postal code**

1981619573

**Phone**

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**Email**

khodabakhshiadeleh@yahoo.com

**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**