Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 metastic breast cancer that will undergo chemotherapy for at least 3 months patient accept follow ketogenic diet for 3 months.Karnofsky index >□70 □ 18 kg/m2 < BMI <34.5 kg/m2 □ Age between 18 and 75 years exclusion criteria: Type I diabetes □ Pregnancy □ 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

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tehran

Province
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1989934148

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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
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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 updating data

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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
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Comments