Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 2026

Assessment of the adjuvant ketogenic diet effect on the therapeutic outcomes of metastatic breast cancer patients

Protocol summary

Study aim
Assessment of the adjuvant ketogenic diet effect on the therapeutic outcomes of metastatic breast cancer patients

Design
This randomized- parallel and open-label clinical trial study (phase 3) will be conducted on 42 metastatic breast cancer patient. Patients will be divided into ketogenic diet and control groups using the block randomization method.

Settings and conduct
In this randomized- parallel and open-label clinical trial study, 42 metastatic breast cancer patients referred to the oncology department of Urmia Imam Khomeini hospital will be enrolled. Patients in the intervention group will be received a ketogenic diet in addition to the standard chemotherapy protocol. The standard chemotherapy protocol will be implemented in the control group.

Participants/Inclusion and exclusion criteria
In this study, patients over 18 years of age with metastatic breast cancer will be included. Patients with lipid metabolism disorders such as carnitine deficiency, patients with liver failure, metastatic liver tissue more than 50%, a history of gastric and pancreatic surgeries, renal cell carcinoma, and type 1 diabetes will be excluded.

Intervention groups
Patients in the intervention group will be received a ketogenic diet in addition to the standard chemotherapy protocol. The standard chemotherapy protocol will be implemented in the control group.

Main outcome variables
Primary tumor size and the metastasis; Vascular endothelium growth factor expression (VEGF); Ketone bodies; Serum albumin; CRP; Quality of life

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210919052515N1**
Registration date: **2021-10-22, 1400/07/30**
Registration timing: **prospective**

Last update: **2021-10-22, 1400/07/30**
Update count: **0**

Registration date
2021-10-22, 1400/07/30

Registrant information
Name
Naser Masoudi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 44 3337 9924
Email address
masoudi.n@umsu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-11-22, 1400/09/01
Expected recruitment end date
2022-02-20, 1400/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Assessment of the adjuvant ketogenic diet effect on the therapeutic outcomes of metastatic breast cancer patients

Public title
The ketogenic diet effect in treatment of metastatic breast cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Metastatic breast cancer patients Age over 18 years
Exclusion criteria:
Lipid metabolism disorders such as carnitine deficiency Patients with liver failure Metastasis more than 50% of liver tissue History of gastric and pancreatic surgeries Renal cell carcinoma Type 1 diabetes
Age
From **18 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into intervention and control groups using the block randomization method. According to the total sample size (42 patients), 7 blocks of 6 will be considered. (A: intervention group and B: control group). so that all possible combinations of AAA BBB will be listed. Then each combination will be given a number of one to seven. A number will be selected randomly for the determination of one of the possible combinations. The randomization process will be continued until the last combination is enrolled. Patients will be divided into two groups according to the order of selected blocks.
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 of Urmia University of Medical Sciences
Street address
Urmia University of Medical Sciences, Resalat Ave, Urmia, Iran.
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2021-09-13, 1400/06/22
Ethics committee reference number
IR.UMSU.REC.1400.219

Health conditions studied

1

Description of health condition studied
Breast cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Primary tumor size and metastasis
Timepoint
Before and three months after the intervention
Method of measurement
With CT scan imaging in millimeters

Secondary outcomes

1

Description
Ketone Bodies
Timepoint
Before and three months after the intervention
Method of measurement
Ketone meter in blood serum (mM/L)

2

Description
Vascular endothelium growth factor expression (VEGF)
Timepoint
Before and three months after the intervention
Method of measurement
Blood serum (Pg/mL)

3

Description
C-Reactive Protein (CRP)
Timepoint
Before and three months after the intervention

Method of measurement
Blood serum (mg/L)

4

Description
Serum albumin
Timepoint
Before and three months after the intervention
Method of measurement
Blood serum sample (gr/dl)

5

Description
Quality of life
Timepoint
Before and three months after the intervention
Method of measurement
Breast cancer-specific quality of life questionnaire (QLQ-BR 23)

Intervention groups

1

Description
Intervention group: Patients will be received the ketogenic diet for three months in addition to the standard chemotherapy protocol. Manuals of this diet will be provided to patients.
Category
Treatment - Other

2

Description
Control group: In the control group, only the standard chemotherapy protocol will be implemented for patients.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia Imam Khomeini Educational hospital
Full name of responsible person
Dr. Naser Masoudi
Street address
Imam Khomeini Educational hospital, Ershad Ave, Modarress Blvd, Urmia, Iran.
City
Urmia
Province
West Azarbaijan
Postal code
5715781351
Phone
+98 44 3345 9538
Email
dr.nasmasoudi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Iraj Mohebbi
Street address
Urmia University of Medical Sciences, Resalat Ave, Urmia, Iran.
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 1930
Email
mohebbi.i@umsu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Dr.Naser Masoudi
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Imam Khomeini hospital, Ershad Ave, Modarres Blvd, Urmia, Iran.
City
Urmia

Province
West Azarbaijan
Postal code
5715781351
Phone
+98 44 3337 9924
Email
dr.nasmasoudi@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Naser Masoudi
Position
Assistant professor
Latest degree
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Other areas of specialty/work
General Surgery
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Province
West Azarbaijan
Postal code
5715781351
Phone
+98 44 3345 9538
Email
dr.nasmasoudi@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Naser Masuodi
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Imam Khomeini hospital, Ershad Ave, Modarress Blvd, Urmia, Iran.
City
Urmia
Province
West Azarbaijan
Postal code
5715781351
Phone
+98 44 3345 9538
Email
dr.nasmasuodi@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The results will be published as an article
When the data will become available and for how long
After the publishing of the article
To whom data/document is available
Researchers
Under which criteria data/document could be used
as published article
From where data/document is obtainable
Corresponding author
What processes are involved for a request to access data/document
If necessary through e-mail addresses of the corresponding author in the published article can have access to the data.
Comments