

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)

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+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		Street address Urmia University of Medical Sciences, Resalat Ave, Urmia, Iran.	
Public title The ketogenic diet effect in treatment of metastatic breast cancer		City Urmia	
Purpose Treatment		Province West Azarbaijan	
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		Postal code 5714783734	
Age From 18 years old		Approval date 2021-09-13, 1400/06/22	
Gender Female		Ethics committee reference number IR.UMSU.REC.1400.219	
Phase 3		Health conditions studied	
Groups that have been masked <i>No information</i>		<u>1</u>	
Sample size Target sample size: 42		Description of health condition studied Breast cancer	
Randomization (investigator's opinion) Randomized		ICD-10 code C50	
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.		ICD-10 code description Malignant neoplasm of breast	
Blinding (investigator's opinion) Not blinded		Primary outcomes	
Blinding description		<u>1</u>	
Placebo Not used		Description Primary tumor size and metastasis	
Assignment Parallel		Timepoint Before and three months after the intervention	
Other design features		Method of measurement With CT scan imaging in millimeters	
Secondary Ids empty		Secondary outcomes	
Ethics committees		<u>1</u>	
<u>1</u>		Description Ketone Bodies	
Ethics committee Name of ethics committee Ethics Committee of Urmia University of Medical Sciences		Timepoint Before and three months after the intervention	
		Method of measurement Ketone meter in blood serum (mM/L)	
		<u>2</u>	
		Description Vascular endothelium growth factor expression (VEGF)	
		Timepoint Before and three months after the intervention	
		Method of measurement Blood serum (Pg/mL)	
		<u>3</u>	
		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

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Imam Khomeini Educational hospital, Ershad Ave,
Modarress Blvd, Urmia, Iran.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

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Urmia University of Medical Sciences, Resalat Ave,
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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

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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