Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effects of Propolis intake on nutritional status, matrix metalloproteinase enzymes, inflammatory, anti-inflammatory and oxidative factors and quality of life in patients with Breast Cancer undergoing chemotherapy.

Protocol summary

Summary

The aim of study is to evaluate the effect of oral administration of propolis on nutritional status, enzymes, matrix metalloproteinases, inflammatory, anti-inflammatory and oxidative markers and quality of life of breast cancer patients will be treated with chemotherapy. Study is the double blind clinical trial and study population are patients with stage II and III breast cancer after surgery which will undergoing chemotherapy. 70 volunteer patients aged 30-50 years with breast cancer will be referred to Tohid Hospital undergoing chemotherapy standard treatment, chemotherapy with the same drugs (adriamycin Neoadjuvant regimen of 60 mg / m2 and cyclophosphamide 600 mg / m2, four Paclitaxel training session once every two weeks and 175 mg / m2 every 3 weeks for four courses), will be included. Patient will be divided in to placebo and propolis group with Block Randomized sampling. A week before the start of chemotherapy, Propolis will be administered in dose of 250 mg twice a day until the end of treatment (3 months) and control group will be received a placebo. Groups' anthropocentric data, dietary intake, nutritional status, quality of life, factors affecting appetite and blood samples will be collected before and after the intervention. Serum levels of interleukins b1,2, 10, TNF-α and oxidant-antioxidant balance, matrix metalloproteinases enzymes 2 and 9, at baseline and after the intervention will be measured. Blinding will be done for the intervention and placebo groups and reviewers of the study's variables.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062828679N1**

Registration date: **2016-09-08, 1395/06/18**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-09-08, 1395/06/18

Registrant information

Name

Seyed Hossein Davoodi

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2235 7483

Email address

hdavoodi1345@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

1.Cancer Research Center, Shahid Beheshti University of Medical Sciences.2. Research Deputy, Kurdistan University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Propolis intake on nutritional status, matrix metalloproteinase enzymes, inflammatory, anti-inflammatory and oxidative factors and quality of life in patients with Breast Cancer undergoing chemotherapy.

Public title
Effects of Propolis intake on nutritional status, some inflammatory and anti-inflammatory factors and quality of life in patients with Breast Cancer undergoing chemotherapy.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Stage II and III Breast cancer under chemotherapy; age range 30 to 50 years. Exclusion criteria: heart disease co morbidity; history of hypersensitivity reactions to bee products.

Age
From **30 years** old to **50 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kurdistan University of Medical Sciences

Street address
Opposite of Shadi Hotel, Pasdaran Str

City
Sanandaj

Postal code

Approval date
2016-06-13, 1395/03/24

Ethics committee reference number
1395/93

Health conditions studied

1

Description of health condition studied
Breast Cancer

ICD-10 code
C50.9

ICD-10 code description
Malignant neoplasm: Breast, unspecified

Primary outcomes

1

Description
Interlukin b1, 2, 10

Timepoint
Baseline and after intervention

Method of measurement
Elisa, ng/ml

2

Description
TNF-α

Timepoint
Baseline and after intervention

Method of measurement
Elisa, ng/ml

3

Description
MMP-2, 9

Timepoint
Baseline and after intervention

Method of measurement
Elisa, ng/ml

4

Description
Anti oxidant Ezymes

Timepoint
Baseline and after intervention

Method of measurement
Elisa, nmol/l

5

Description
Nutritional Status

Timepoint
Baseline and after intervention

Method of measurement
PGSGA questionner

6

Description
mir 21

Timepoint

Baseline and after intervention

Method of measurement

Fold

7

Description

mir638

Timepoint

Baseline and after intervention

Method of measurement

Fold

8

Description

quality of life

Timepoint

Baseline and after intervention

Method of measurement

EORTC QLQ30

Secondary outcomes

1

Description

Chemotrapy Complication

Timepoint

Baseline and after intervention

Method of measurement

questionner

2

Description

Liver Enzymes

Timepoint

Baseline and after intervention

Method of measurement

Eliza, IU/L

Intervention groups

1

Description

A week before the start of chemotherapy in intervention group, 250 mg propolis extract divided in two 125 mg capsules will administered twice daily with breakfast and lunch until the end of treatment (3 months).

Category

Treatment - Drugs

2

Description

A week before the start of chemotherapy in the placebo group, starch capsules with dose of 250 mg (125 mg twice daily) will administered with breakfast and lunch until the end of treatment (3 months)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tohid Hospital of Sanandaj

Full name of responsible person

Dr Bayezid Ghaderi

Street address

Oncology Ward, Tohid Hospital, Gheryashan Blvd

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Reaerch Deputy of Kurdistan University of Medical Sciences

Full name of responsible person

Dr Ebrahim Ghaderi

Street address

Pasdaran Str, Reaerch Deputy of Kurdistan University of Medical Sciences

City

Sanandaj

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Reaerch Deputy of Kurdistan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nazila Darvishi

Position

PhD Candidate of Nutrition

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty