# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Jun 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 scientific inquiries

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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*