

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effect of herbal marine compound (HESE-A) on Quality of life in women with breast cancer in medical centers in Bushehr city in 1394

Protocol summary

Summary

The aim of this study is Effect of herbal marine compound (HESE-A) on Quality of life in women with breast cancer Inclusion criteria: age above 18 years and below 60 years, diagnosis of breast cancer by oncologist and pathologist physician, History of at least one course of chemotherapy Exclusion criteria: Forgor pills Hesa - A for five consecutive times or more, Use of medication or other treatment methods to reduce the effects of other common medications prescribed by the doctor Single-blind, controlled study randomized clinical trial of chemotherapy at the center of the city of Bushehr on 72 women with breast cancer undergoing chemotherapy will be done. After selecting 72 female patients with breast cancer among all patients, 36 patients were divided into two groups: the intervention group (drug Hsa-A) and control group (placebo) will be. The intervention and control groups after chemotherapy treatments , Hesa-a daily one tablet orally (50 mg) will start and lasts for three months and the control group patients received placebo capsules daily Through oral . Quality of life in patients before the intervention, 45 and 90 days after treatment is assessed via questionnaire

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112322466N8**

Registration date: **2016-01-31, 1394/11/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-31, 1394/11/11

Registrant information

Name

Shahnaz Pouladi

Name of organization / entity

Bushehr University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 917 374 0061

Email address

sh.pooladi@bpums.ac.ir

Recruitment status

Recruitment complete

Funding source

Bushehr University of Medical Sciences

Expected recruitment start date

2016-01-30, 1394/11/10

Expected recruitment end date

2016-07-31, 1395/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of herbal marine compound (HESE-A) on Quality of life in women with breast cancer in medical centers in Bushehr city in 1394

Public title

Effect of herbal marine compound (HESE-A) on Quality of life in women with breast cancer in medical centers in Bushehr city in 1394

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age above 18 years and below 60 years, diagnosis of breast cancer oncologist and pathologist doctor (stage 3 and 4); history of at least one

course of chemotherapy, no history of drug allergy Hsa-A
Exclusion criteria from the study include: Forgot pills
Hesa - A for five consecutive times or more, the use of
drugs or other treatment methods to reduce the effects
of other common medications prescribed by your doctor;
the risk of problems and severe gastrointestinal side
effects during the study, and eventually the desire to
continue to participate in the study.

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Bushehr University of Medical Sciences

Street address

Bushehr University of Medical Sciences, Bushehr Iran

City

Bushehr

Postal code**Approval date**

2015-11-14, 1394/08/23

Ethics committee reference number

bpums.res.1394.23

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**

Quality of Life

Timepoint

Before the study, 45 days and 90 days after treatment

Method of measurement

questionnaire

Secondary outcomes**1****Description**

Quality of Life

Timepoint

Before the study, 45 days and 90 days after treatment

Method of measurement

questionnaire

Intervention groups**1****Description**

The control group received placebo capsules (identical in shape Hesa-a capsules) One capsule (50 mg) daily through orally for three months

Category

Placebo

2**Description**

In the intervention group after a course of chemotherapy (second or more) on a daily basis Hesa-a orally one tablet (50 mg) will start for three months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hospital Bushehr Persian Gulf: Osfuri Doctor's office :
Ravanbod Doctor's office

Full name of responsible person

Roohollahesmati: Master Nursing Student

Street address

Amiralmomenin Hospital, Bushehr, Iran

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bushehr University of Medical Sciences

Full name of responsible person

Dr. Afshin Ostovar

Street address

Research Center, Bushehr University of Medical Sciences , Sabzabad

City

Bushehr

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bushehr 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

Bushehr University of Medical Sciences

Full name of responsible person

DR. Shahnaz Pouladi

Position

Nursing Ph.D.

Other areas of specialty/work

Street address

Bushehr-Bushehr University of Medical Sciences-
College of Nursing and Midwifery

City

Bushehr

Postal code

Phone

+98 77 3345 0178

Fax

Email

Pouladi2008@yahoo.comSh.Pooladi@bpums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bushehr University of Medical Sciences

Full name of responsible person

DR . Shahnaz Pouladi

Position

Nursing Ph.D.

Other areas of specialty/work

Street address

Bushehr University of Medical Sciences

City

Bushehr

Postal code

Phone

+98 77 3345 0178

Fax

Email

Pouladi2008@yahoo.comSh.Pooladi@bpums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Bushehr University of Medical Sciences

Full name of responsible person

Dr. Shahnaz Pouladi

Position

Nursing Ph.D

Other areas of specialty/work

Street address

Bushehr University of Medical Sciences-college of
Nursing and Midwifery

City

Bushehr

Postal code

Phone

+98 77 3345 0178

Fax

Email

Pouladi2008@yahoo.comSh.Pooladi@bpums.ac.ir

Web page address

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