Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the effect of Beta-D mannuronic acid on processing of breast cancer disease

Protocol summary

Summary

The beta-D-mannuronic acid is an anti-inflammatory agent that belongs to the family of nonsteroidal anti-inflammatory drugs that it has shown the therapeutic effects with the greatest tolerability and safety in various experimental models. The aim of this study is to assess the safety and efficacy of beta-D-mannuronic acid in treatment of patients with breast cancer. In this study the most important inclusion criteria are histopathological certain results and tumoral mass existance, and the most important exclusion criteria are existance of infectious diseases and concomitant diseases. In this randomized, controlled trial, 36 patients with breast cancer fulfilling the American College of oncology Diagnostic Criteria will be examined. Patients will be randomly assigned to receive either beta-D-mannuronic acid (treatment group, 24 patients) with administration of three 500 mg tablets/day or conventional drugs (control group, 12 patients) orally for 12 weeks. The tumor size and serum level of CEA and CA15.3, will be evaluated at baseline and 12 weeks after treatment. In this study basically changes of tumor size and serum level of CA15.3 and CEA factors befor and after treatment with this drug as the most important results this study will be examined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012213739N7**
Registration date: **2017-02-05, 1395/11/17**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-02-05, 1395/11/17

Registrant information

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Abbas Mirshafiey
Name of organization / entity
Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research, Tehran University of Medical Sciences and

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Beta-D mannuronic acid on processing of breast cancer disease

Public title

The therapeutic effect of Beta-D mannuronic acid in breast cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 30-60 years old patients, Diagnosed with breast cancer according to American College of oncology Diagnostic Criteria after the initial visit by a

specialist in cancer surgery and parameters CEA, CA15.3, CBC and sonography, Each patient must sign written informed consent. Exclusion Criteria: History of fever and Infectious diseases, Positive pregnancy test or Lactation, Other collagen- vascular and auto immune diseases, Patients have enrolled another clinical trial study within last 4 weeks, Other concomitant diseases (Hepatic, renal, haematological, gastrointestinal, endocrine, cardiovascular, pulmonary, neurological or cerebral disease).

Age
From **65 years** old to **35 years** old

Gender
Female

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double 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 Tehran University of Medical Sciences

Street address
6th floor، central building of Tehran University of Medical Sciences، On the Corner of Keshavarz Blv

City
Tehran

Postal code

Approval date
2017-01-21, 1395/11/02

Ethics committee reference number
IR.TUMS.SPH.REC.1395.1490

Health conditions studied

1

Description of health condition studied
Breast cancer

ICD-10 code
C50.8

ICD-10 code description
Malignant neoplasm: overlapping lesion of breast

2

Description of health condition studied
Breast cancer

ICD-10 code
C50.2

ICD-10 code description
Malignant neoplasm: upper-inner quadrant of breast

3

Description of health condition studied
Breast cancer

ICD-10 code
C50.3

ICD-10 code description
Malignant neoplasm: lower-inner quadrant of breast

4

Description of health condition studied
Breast cancer

ICD-10 code
C50.4

ICD-10 code description
Malignant neoplasm: upper-outer quadrant of breast

5

Description of health condition studied
Breast cancer

ICD-10 code
C50.5

ICD-10 code description
Malignant neoplasm: lower-outer quadrant of breast

6

Description of health condition studied
Breast cancer

ICD-10 code
C50.6

ICD-10 code description
Malignant neoplasm: axillary tail of breast

7

Description of health condition studied
Breast cancer

ICD-10 code
C50.9

ICD-10 code description
Malignant neoplasm: breast, unspecified

8

Description of health condition studied
Breast cancer

ICD-10 code

C50.0

ICD-10 code description

Malignant neoplasm: nipple and areola

Primary outcomes

1

Description

Feel the mass and tenacity in breast

Timepoint

At baseline and after 12 weeks of treatment

Method of measurement

Examination by specialist

Secondary outcomes

1

Description

Tumor size

Timepoint

At baseline and after 12 weeks of treatment

Method of measurement

Sonography

Intervention groups

1

Description

The intervention group will receive 1500 mg/day (three 500 mg tablets/day) of beta-D mannuronic acid orally for 12 weeks. The beta-D mannuronic acid produced from the decomposition of Alginate powder (a safe, natural substance used in food and pharmaceutical industries) purchased from Sigma Corporation of U.S.A, in central laboratory of immunology department of School of Public Health and Institute of Health Research of Tehran University of Medical Sciences.

Category

Treatment - Drugs

2

Description

Control group will receive of conventional drugs orally for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Institute Of Emam Khomeini Hospital

Full name of responsible person

Dr. Habib allah Mahmodzade (MD. cancer sergeon)

Street address

Cancer Institute, Emam Khomeini Hospital,Keshavarz blv, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Masood Younesian (MD, PhD, Vice-Chancellor for Research, Tehran University of Medical Sciences)

Street address

6th floor, central building of Tehran University of Medical Sciences, On the Corner of Keshavarz Blvd. and Qods Street, Keshavarz Blvd., Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-Chancellor for Research, Tehran 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

Department of pathobiology, School of Public Health, Tehran University of Medical Sciences

Full name of responsible person

Dr. Abbas Mirshafiey

Position

Head of the Department of pathobiology (PHD - Professor)

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

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Name of organization / entity

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Web page address

Person responsible for updating data

Contact

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