

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effects of Cydonia Oblonga Mill. fruit syrup on reduction of Biochemical complications induced by Trastuzumab (Herceptin) in patients with breast cancer: A randomized double blind clinical trial study

Protocol summary

Study aim

Determining the Effects of quince Fruit Extract in Reducing Biochemical Complications from Prescribing Herceptin in Patients with Breast Cancer

Design

Participants are randomly assigned to two groups of syrups containing blueberry fruit extract and placebo.

Settings and conduct

The study population will be randomly selected from HER2-positive breast cancer patients referred to clinics and hospitals affiliated with Zanjan University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Criteria for entering include: willingness to participate in the study, breast cancer in the early stages of the disease, positive HER2, women over 18 years, life expectancy of more than 3 months, the person is at least able to walk and do Be your own personal affairs. Exclusion include: other cancers, thyroid or kidney disorders, receiving other vitamin or mineral supplements, patients with a body mass index of less than 18.5 and no The desire to continue participating in the project is for any reason.

Intervention groups

The group receiving the syrup contains the blue fruit extract and the group receiving the placebo

Main outcome variables

At the beginning of the study, a general and clinical information questionnaire, a food frequency questionnaire, and a nutritional status questionnaire for patients will be completed. Measurement and body composition measurements will be performed at the beginning and end of the study for patients. Blood sampling for biochemical, antioxidant and blood levels of biomarkers related to cardiac poisoning caused by prescribing herceptin in this disease will be performed at the beginning and end of the study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200427047219N2**

Registration date: **2020-05-31, 1399/03/11**

Registration timing: **prospective**

Last update: **2020-05-31, 1399/03/11**

Update count: **0**

Registration date

2020-05-31, 1399/03/11

Registrant information

Name

Mohammad Reza Eskandari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3347 3635

Email address

eskandarimr@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-05, 1399/06/15

Expected recruitment end date

2021-09-06, 1400/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of Cydonia Oblonga Mill. fruit syrup on reduction of Biochemical complications induced by Trastuzumab (Herceptin) in patients with breast cancer: A randomized double blind clinical trial study

Public title

Evaluation of the effects of Cydonia Oblonga Mill. fruit syrup on reduction of Biochemical complications induced by Herceptin in patients with breast cancer

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

The desire to participate in the study Breast cancer in the early stages of the disease HER2 positive Women over 18 years Life expectancy more than 3 months (with a doctor's diagnosis) A person should at least be able to walk and do their own thing (WHO performance status 0-2)

Exclusion criteria:

Suffering from other cancers Thyroid or kidney disorders Get other vitamin or mineral supplements Patients with a body mass index less than 18.5 Lack of willingness to continue participating in the project for any reason

Age

From **18 years** old

Gender

Female

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

This study will be a two-course clinical trial. The study population will be randomly selected from patients with HER2-positive breast cancer who go to clinics and hospitals affiliated with Zanjan University of Medical Sciences. Diagnosis will be made by an oncologist using blood tests, ultrasound, and, if necessary, additional procedures.

Blinding (investigator's opinion)

Double blinded

Blinding description

The container containing the extract and placebo will be uniform in appearance, and patients, as well as researchers, will be blind to the content of the contents of the bottles during the study and whether participants will receive the extract or placebo. For the preparation of placebo syrup, the base of the main syrup is used without extract, and for the uniformity of the shape, taste and smell of both types and types of syrup, apple essential oil and food coloring are allowed in very low doses. These syrups are made of sugar and according to the usp. Containers containing placebo and extract are

coded by a third party and delivered to patients.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Committee of Animal Experimentation of Zanjan University of Medical Sciences, Zanjan

Street address

Azadi Blvd., Central Headquarters of Zanjan University of Medical Sciences, Second Building, Third Floor, Deputy of Research and Technology

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2020-01-11, 1398/10/21

Ethics committee reference number

IR.ZUMS.REC.1399.072

Health conditions studied**1****Description of health condition studied**

Breast cancer

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Biochemical factors including: ALP,GGT,ALT, AST

Timepoint

At the beginning of the experiment and 3 months after the intervention

Method of measurement

Laboratory kits

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

Biochemical factors

Timepoint

Start of study (before the start of the intervention) and 3 months later

Method of measurement

Laboratory kits

Intervention groups

1

Description

Intervention group: Patients with breast cancer receiving quince syrup

Category

Prevention

Recruitment centers

1

Recruitment center**Name of recruitment center**

Valiasr Hospital

Full name of responsible person

Mohammad Reza Eskandari

Street address

Sheikh Fazlollah Nouri Highway, above Valiasr Square

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77978-45157

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Deputy Minister of Research and Technology

Street address

Azadi Blvd., Central Headquarters of Zanjan University of Medical Sciences, Second Building, Third Floor

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research@zums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Zanjan 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**

Zanjan University of Medical Sciences

Full name of responsible person

Mohammad Reza

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available