Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 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
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Iran (Islamic Republic of)
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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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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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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
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Mohammad Reza
Position
Associate professor
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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