Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effects of quince (Cydonia Oblonga Mill.) fruit syrup on reduction of cardiotoxicity induced by Trastuzumab (Herceptin) in patients with breast cancer

Protocol summary

Study aim

Determining the Effects of Blue Fruit Extract to (Cydonia Oblonga Mill) on Reducing Heart Complications from Prescribing Trastuzomab (Herceptin) in Patients with Breast Cancer

Design

Samples will be selected from breast cancer patients who have been diagnosed with the disease for the first time. After reviewing the criteria for entering and exiting the study and explaining and obtaining informed consent, patients will be randomly assigned to one of the two groups receiving fruit blueberry extract to (A) or placebo (B).

Settings and conduct

This study will be a two-course clinical trial. The study population will be randomly selected from HER2-positive breast cancer patients referred to the clinic and hospital affiliated to Zanjan University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Criteria for entering the study include: willingness to participate in the study, breast cancer in the early stages of the disease, HER2 positive, women over 18 years and the absence of underlying heart problems and criteria for leaving the study include: other cancers, thyroid disorders or Kidney, receiving other vitamin or mineral supplements, patients with a body mass index of less than 18.5 and also a reluctance to continue participating in the project for any reason.

Intervention groups

After reviewing the criteria for entering and exiting the study and explaining and obtaining informed consent, patients will be randomly assigned to one of the two groups receiving fruit blueberry extract to (A) or placebo (B).

Main outcome variables

Patients will start taking fruit syrup at the same time as receiving the first dose of herceptin and will receive the syrup daily for three months. All patients will be examined at the beginning and end of three months for cardiac factors, including echocardiographic results (left ventricular esophagus) and ECG.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200427047219N1**
Registration date: **2020-05-10, 1399/02/21**
Registration timing: **prospective**

Last update: **2020-05-10, 1399/02/21**
Update count: **0**

Registration date

2020-05-10, 1399/02/21

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

2020-07-05, 1399/04/15

Expected recruitment end date

2022-07-06, 1401/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of quince (Cydonia Oblonga Mill.) fruit syrup on reduction of cardiotoxicity induced by Trastuzumab (Herceptin) in patients with breast cancer

Public title

Effects of quince fruit syrup on reduction of cardiotoxicity induced by Herceptin in patients with breast cancer

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Breast cancer in the early stages of the disease HER2 positive Women over 18 years Lack of underlying heart problems The desire to participate in the study

Exclusion criteria:

Suffering from other cancers Thyroid disorders Kidney disorders Getting other vitamin or mineral supplements Patients with lower body mass index18/5 Lack of desire to continue participating in the project

Age

From **38 years** old

Gender

Female

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple accidental

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and researchers will be unaware of the contents of the bottles during the study and whether participants will receive the extract or placebo. 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

Zanjan University of Medical Sciences, Ethics Committee

Street address

زنجان، بلوار آزادی، ستاد مرکزی دانشگاه علوم پزشکی زنجان، ساختمان دوم، طبقه سوم، معاونت تحقیقات و فناوری

City

ZANJAN

Province

Zanjan

Postal code

4515613191

Approval date

2020-01-16, 1398/10/26

Ethics committee reference number

IR.ZUMS.REC.1393.413

Health conditions studied

1

Description of health condition studied

Patients with breast cancer who are taking herceptin

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

1. Determining the effect of quince syrup on cardiac function-related factors (left ventricular emptying fraction) in patients with breast cancer receiving fruit syrup by comparison with patients with breast cancer receiving placebo. 2- Determining the effect of quince syrup on the findings of ECG in patients with breast cancer receiving the syrup compared to patients receiving placebo.3. Determining the effect of quince syrup on the plasma levels of troponin I in patients with breast cancer receiving fruit syrup who have evidence of cardiomyopathy by comparing them with patients with breast cancer receiving placebo who have evidence of cardiomyopathy.4. Determining the effect of quince syrup on creatinine plasma plasma levels in patients with breast cancer receiving fruit syrup by comparing with patients with breast cancer receiving placebo

Timepoint

Patients will drink the syrup daily with some water for three months. The placebo will appear in the same bottles as the intervention group. The syrup bottles and placebo are given to patients on a monthly basis, and the researcher will follow up on the consumption or report possible side effects on the phone and on a weekly basis.

Method of measurement

Blood sampling to check the blood levels of biomarkers

related to cardiac poisoning caused by prescribing herceptin in this disease will be done at the beginning and end of the study, ie 3 months later.

Secondary outcomes

1

Description
1- Receiving fruit syrup has an effect on heart function factors (left ventricular emptying fraction) in patients with breast cancer. 2- Receiving fruit syrup has an effect on the findings of ECG in patients with breast cancer. Fruit syrup affects the amount of troponin I in patients with breast cancer who have had cardiomyopathy. 4. Fruit syrup intake affects the amount of creatine kinase in patients with breast cancer.

Timepoint
At the beginning of the study (before the start of the intervention) and 3 months after the start of the syrup

Method of measurement
Ventricular drainage fraction by echocardiography and troponin I by immunoenzymatic fluorescent assay

Intervention groups

1

Description
Intervention group: Patients with breast cancer who take herceptin and take syrup with it

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Valiasr Hospital

Full name of responsible person
Mohammad Reza

Street address
Valiasr Medical Center, above Valiasr Square, Sheikh Fazlollah Nouri Highway

City
Zanjan

Province
Zanjan

Postal code
77978-45157

Phone
+98 24 3377 0801

Fax
+98 24 3377 0751

Email
valiasr@zums.ac.ir

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

City
Zanjan

Province
Zanjan

Postal code
4515613191

Phone
+98 24 3315 6130

Email
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

Street address
Department of Pharmacology and Toxicology, School of Pharmacy, Zanjan University of Medical Sciences, 45139-56184 Zanjan, Iran

City
Zanjan

Province

Zanjan
Postal code
45139-56184
Phone
+98 24 3347 3638
Email
eskandarimr@zums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Mohammad Reza Eskandari
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Toxicology
Street address
Department of Pharmacology and Toxicology, School of Pharmacy, Zanjan University of Medical Sciences, Zanjan, Iran, Postal Code: 45139-56184
City
Zanjan
Province
Zanjan
Postal code
45139-56184
Phone
+98 24 3347 3635
Fax
+98 24 3347 3639
Email
eskandarimr@zums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Mohammad Reza Eskandari
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Toxicology
Street address
Department of Pharmacology and Toxicology, School of Pharmacy, Zanjan University of Medical Sciences, Zanjan, Iran, Postal Code: 45139-56184
City
Zanjan
Province
Zanjan
Postal code
45139-56184
Phone
+98 24 3347 3635
Fax
+98 24 3347 3639
Email
eskandarimr@zums.ac.ir

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