Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Post-marketing surveillance for evaluation of AryoTrust safety in Iranian HER2-positive breast cancer patients under adjuvant chemotherapy regimens

Protocol summary

Study aim
Evaluation of AryoTrust safety and adverse effects in Iranian HER2-positive breast cancer patients under adjuvant chemotherapy regimens

Design
The present study is a phase 4 clinical trial aimed to investigate 597 patients with non-metastatic HER2 positive breast cancer after treatment with adjuvant chemotherapy. Data collection is done through interviews, physical examination and adverse reactions which are recorded in specific notebooks. There are two notebooks, first notebook consists of cycles 1 to 3 and second notebook consists of cycles 4 to 9 and is completed in patients who can be followed after 3 trastuzumab administration, according to investigator's decision.

Settings and conduct
The present study is conducted due to interview, physical examination and adverse reactions recording in notebooks. This phase 4 study is performed in Iran, on Iranian breast cancer patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients diagnosed with non-metastatic HER2 positive breast cancer after treatment with adjuvant chemotherapy (trastuzumab in combination with doxetaxel or paclitaxel weekly for 12 weeks or others regimens) who are candidates for trastuzumab maintenance therapy 6 mg/kg every 3 weeks for 12 months. Exclusion criteria: Patients who received Herceptin, Patients who are not candidates for trastuzumab maintenance therapy after adjuvant chemotherapy.

Intervention groups
Trastuzumab maintenance therapy 6 mg/kg every 3 weeks for 12 months after treatment with adjuvant chemotherapy

Main outcome variables
AryoTrust safety and adverse effects

General information

Reason for update

Acronym
مطالعه پایش ایمنی داروی آریوتراست

IRCT registration information
IRCT registration number: **IRCT20150303021315N16**
Registration date: **2019-11-24, 1398/09/03**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-24, 1398/09/03**
Update count: **0**

Registration date
2019-11-24, 1398/09/03

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-12-22, 1396/10/01

Expected recruitment end date
2020-03-18, 1398/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Post-marketing surveillance for evaluation of AryoTrust safety in Iranian HER2-positive breast cancer patients under adjuvant chemotherapy regimens

Public title
Evaluation of AryoTrust administration in treatment of breast cancer
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Patients diagnosed with non-metastatic HER2 positive breast cancer after treatment with adjuvant chemotherapy (trastuzumab in combination with doxetaxel or paclitaxel weekly for 12 weeks or others regimens) who are candidates for trastuzumab maintenance therapy 6 mg/kg every 3 weeks for 12 months
Exclusion criteria:
- Patients who received Herceptin - Patients who are not candidates for trastuzumab maintenance therapy after adjuvant chemotherapy
Age
From **18 years** old
Gender
Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **597**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Regional ethics committee of Mashhad university of medical sciences
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Research chancellor, Mashhad University of Medical Sciences, 18th Daneshgah St., Daneshgah Ave.
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Approval date
2017-11-15, 1396/08/24
Ethics committee reference number
IR.MUMS.fm.REC.1396.519

Health conditions studied

1

Description of health condition studied
Breast cancer
ICD-10 code
C50.919
ICD-10 code description
Malignant neoplasm of unspecified site of unspecified female breast

Primary outcomes

1

Description
Ejection fraction decreased
Timepoint
Every 3 weeks
Method of measurement
echocardiography

2

Description
Peripheral oedema
Timepoint
Every 3 weeks
Method of measurement
physical examination

3

Description
Tachycardia
Timepoint
Every 3 weeks
Method of measurement
heart rate counting

4

Description
Hypotension
Timepoint
Every 3 weeks
Method of measurement

blood pressure meter

5

Description
Hypertension
Timepoint
Every 3 weeks
Method of measurement
blood pressure meter

6

Description
Nausea- Vomiting- Diarrhoea- Abdominal pain
Timepoint
Every 3 weeks
Method of measurement
medical history and physical examination

7

Description
Headache- Fatigue- Insomnia- Dizziness- Paresthesia
Timepoint
Every 3 weeks
Method of measurement
Medical history and physical examination

8

Description
Neutropenia- Anaemia- Febrile neutropenia
Timepoint
Every 3 weeks
Method of measurement
CBC complete blood count

9

Description
Rash- Nail disorder
Timepoint
Every 3 weeks
Method of measurement
physical examination

10

Description
Arthralgia- Bone pain- Back pain
Timepoint
Every 3 weeks
Method of measurement
Medical history and physical examination

11

Description
Chills- Pyrexia- Angioedema
Timepoint
Every 3 weeks
Method of measurement
thermometer

12

Description
Influenza like illness- Infection
Timepoint
Every 3 weeks
Method of measurement
lab data

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients are treated with 6mg/kg trastuzumab (produced by AryoGen pharmed) every 3 weeks in adjuvant setting, for 12 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Omid Hospital
Full name of responsible person
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Sponsors / Funding sources

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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
Aryogen
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no intention for the company to do.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available