

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

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

#### Protocol summary

AryoTrust safety and adverse effects

##### 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 doxorubicin 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

#### 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

##### Name

Nassim Anjidani

##### Name of organization / entity

Orchid Pharmed

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4347 3000

##### Email address

amini@orchidpharmed.com

##### 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 doxorubicin 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

**Street address**

Research chancellor, Mashhad University of Medical Sciences, 18th Daneshgah St., Daneshgah Ave.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91735951

**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**

Dr. Fatemeh Homaei Shandiz

##### **Street address**

koohsangi Ave., Alandasht Sq.

##### **City**

Mashhad

##### **Province**

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##### **Postal code**

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##### **Phone**

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### 2

#### **Recruitment center**

##### **Name of recruitment center**

Imam Reza hospital

##### **Full name of responsible person**

Dr Roham Salek

##### **Street address**

Imam Reza Hospital Sq.

##### **City**

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##### **Province**

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9137913316

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+98 51 3854 3031

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SalekR@mums.ac.ir

**3****Recruitment center****Name of recruitment center**

Golestan Hospital

**Full name of responsible person**

Dr Mohammad Hoseini

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Farvardin Ave.

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Ahwaz

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Khouzestan

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3311861357

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kiahossainy@yahoo.com

**4****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital

**Full name of responsible person**

Dr Farhad Sameiee

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Keshavarz Blvd.

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Tehran

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**5****Recruitment center****Name of recruitment center**

Shohadaye Tajrish Hospital

**Full name of responsible person**

Dr Hamidreza Mirzaei

**Street address**

Tajrish Sq.

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**6****Recruitment center****Name of recruitment center**

Imam Hosein Hospital

**Full name of responsible person**

Dr Robab Anbeiaei

**Street address**

Shahid Madani st.

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**7****Recruitment center****Name of recruitment center**

Sayedoshohada Hospital

**Full name of responsible person**

Dr Simin Hemmati

**Street address**

motahari St.

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**8****Recruitment center****Name of recruitment center**

7th Tir Hospital

**Full name of responsible person**

Dr Alireza Nikoofar

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Shahid Rajaei St.

**City**

Tehran

**Province**

Tehran

**Postal code**

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**9****Recruitment center**

**Name of recruitment center**  
Firouzgar Hospital  
**Full name of responsible person**  
Dr Amir Mohammad Arefpour  
**Street address**  
Valiasr Sq.  
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## 10

**Recruitment center**  
**Name of recruitment center**  
Namazi Hospital  
**Full name of responsible person**  
Dr Ahmad Mosallaei  
**Street address**  
Zand St.  
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+98 71 3647 4332  
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## 11

**Recruitment center**  
**Name of recruitment center**  
Razavi Hospital  
**Full name of responsible person**  
Dr Fahimeh Khoshrou  
**Street address**  
Azadi highway  
**City**  
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Razavi Khorasan  
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**Email**  
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## 12

**Recruitment center**  
**Name of recruitment center**  
Imam Reza Hospital  
**Full name of responsible person**

Dr Fatemeh Nosrati  
**Street address**  
Bojnord  
**City**  
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**Province**  
North Khorasan  
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**Email**  
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## 13

**Recruitment center**  
**Name of recruitment center**  
Khansari Hospital  
**Full name of responsible person**  
Dr Fathollah Mohaghegh  
**Street address**  
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**Province**  
Markazi  
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## 14

**Recruitment center**  
**Name of recruitment center**  
Imam Khomeini Hospital  
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Dr Maziyar Kani  
**Street address**  
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**City**  
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**Recruitment center**  
**Name of recruitment center**  
Omod Hospital  
**Full name of responsible person**  
Dr Omid Esnaashari  
**Street address**  
Urumia

**City**  
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West Azarbaijan  
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## 16

**Recruitment center**  
**Name of recruitment center**  
shahid Madani Hospital  
**Full name of responsible person**  
Dr Reza Eghdam Zamiri  
**Street address**  
Tabriz  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
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## 17

**Recruitment center**  
**Name of recruitment center**  
Ali ebne abi taleb Hospital  
**Full name of responsible person**  
Dr Mojtaba Tasbandi  
**Street address**  
Zahedan  
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Zahedan  
**Province**  
Sistan-va-Balouchestan  
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## 18

**Recruitment center**  
**Name of recruitment center**  
Imam Khomeini Hospital  
**Full name of responsible person**  
Dr Arash Ghasemi  
**Street address**  
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Mazandaran  
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## 19

**Recruitment center**  
**Name of recruitment center**  
Velayat Hospital  
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Dr Jalaledin Rafieei  
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Qazvin  
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## 20

**Recruitment center**  
**Name of recruitment center**  
Shafa Hospital  
**Full name of responsible person**  
Dr Mohammad Hasan Lari zadeh  
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Kerman  
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**Province**  
Kerman  
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## 21

**Recruitment center**  
**Name of recruitment center**  
Imam Reza Hospital  
**Full name of responsible person**  
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**City**  
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## 22

### Recruitment center

**Name of recruitment center**  
Fifth Azar Hospital  
**Full name of responsible person**  
Dr Reza Khandoozi  
**Street address**  
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**Province**  
Golestan  
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**Email**  
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## 23

### Recruitment center

**Name of recruitment center**  
Mahdiyeh Radiotherapy center  
**Full name of responsible person**  
Dr Kamal Mohammadiyan  
**Street address**  
Hamedan  
**City**  
Hamedan  
**Province**  
Hamadan  
**Postal code**  
9176613775  
**Phone**  
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**Email**  
Homaeef@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Aryogen  
**Full name of responsible person**  
Dr Amir Farshchi  
**Street address**  
Jaddeh makhsous  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
9172352352

**Phone**  
+98 26 3610 6480  
**Email**  
info@aryogen.com

#### 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

### Contact

**Name of organization / entity**

orchid pharmed co

**Full name of responsible person**

Banafshe Ghomian

**Position**

Clinical Research Associate

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Others

**Street address**

Attar Sq.

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**Province**

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**Postal code**

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**Phone**

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**Email**

ghomian.b@orchidpharmed.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Fatemeh Homaei

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Radiotherapy  
**Street address**  
Koohsangi Ave.

**City**  
Mashhad

**Province**  
Razavi Khorasan

**Postal code**  
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**Email**  
HomaeeF@mums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Orchid pharmed co

**Full name of responsible person**  
Banafshe Ghomian

**Position**  
Clinical Research Associate

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Others

**Street address**  
Attar Sq.

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**Email**  
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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