

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### A randomized, double blind clinical trial to evaluate biosafety of trastuzumab produced by aryogen company (™ Hercease) in comparison to Roche company trastuzumab (™ Herceptin)

#### Protocol summary

##### Summary

purpose: evaluation of aryogen trastuzumab biosafety. design: A randomized clinical trial to evaluate biosafety of trastuzumab produced by aryogen (™ Hercease) in comparison to ™ Herceptin. setting and conduct: first all staff will be educated through conducting the trial and then patient assessment will be held by surgeon. after introducing patients, Filing, assining the 6 digit code to every patient and giving it to pharmacist to determine the intervention group will be done. eligible patients will be treated by chemotherapy 12 weeks after breast surgery. inclusion criteria: female with age between 18 - 70 years; HER2+ breast cancer. exclusion criteria: bilateral metastatic breast cancer; other malignancies; renal, liver and bone marrow insufficiency; intervention time: from April 26, 2014 up to 1 year. chemotherapy regimen: first we inject Docetaxel (100mg/m2) in days 1,22 and 43. also infusion of trastuzumab (4mg/kg) as loading dose at first day and 2mg/kg as maintenance dose in days 8, 15, 22, 29, 36, 43, 50 and 57 via IV route. after that in 3 periods with 3 weeks interval we will infuse 5FU 600mg/m2, Cyclophosphamide 600mg/m2 and Epirubicin 60mg/m2 at first day of each interval. patients in control group will receive the same regimen in test group but with trastuzumab of aryogen. primary outcome measures include incidence of drug related adverse effects, and clinical information. secondary outcomes include: ECOG grade, blood test for evaluation of blood factors and EEG for assessment of cardiac arrhythmia.

#### General information

##### Acronym

TRA.ARY.KM.92

##### IRCT registration information

IRCT registration number: **IRCT2015090621315N2**

Registration date: **2015-10-14, 1394/07/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-10-14, 1394/07/22

##### 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

Aryogen pharmaceutical company

##### Expected recruitment start date

2014-04-26, 1393/02/06

##### Expected recruitment end date

2015-04-26, 1394/02/06

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A randomized, double blind clinical trial to evaluate biosafety of trastuzumab produced by aryogen company

(™Hercease) in comparison to Roche company  
trastuzumab (™Herceptin)

IR.ACECR.IBCRC.REC.1394.3

## Public title

biosafety assesment of aryogen company trustuzumab  
(™Hersease) in breast cancer

## Purpose

Treatment

## Inclusion/Exclusion criteria

inclusion criteria: female aged 18- 70 years at the time of  
signing the informed consent form; HER2+ breast cancer  
in ich experiment with 3+ and or 2+ that has reported  
positive by FISH method; ECOG grade between 0-1; LVEF  
55% or more. exclusion criteria: bilateral metastatic  
breast cancer; other malignancies; renal, liver, bone  
marrow and cardiac insufficiencies; hypertention;  
pregnancy or planning to be pregnant.

## Age

From **18 years** old to **70 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **20**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

randomization method: balanced block randomization  
with concealment

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

ethics committee of jihad-e-daneshgahi breast cancer  
institute

##### Street address

NO45- west shahid nazari st- aboureyhan st-  
enghelab e eslami st

##### City

Tehran

##### Postal code

#### Approval date

2015-08-23, 1394/06/01

#### Ethics committee reference number

### 2

#### Ethics committee

##### Name of ethics committee

Isfahan university of medical science, Medical Ethics  
Committee

##### Street address

:International Bureau, Isfahan University of Medical  
Sciences, P.O. Box 319, Hezar-Jerib Ave., Isfahan, IR  
Iran, 81746 73461

##### City

Esfahan

##### Postal code

#### Approval date

2016-07-17, 1395/04/27

#### Ethics committee reference number

IR.MUI.REC.1395.04.041

## Health conditions studied

### 1

#### Description of health condition studied

Benign neoplasm of breast

#### ICD-10 code

D24

#### ICD-10 code description

Benign neoplasm of connective tissues and soft parts of  
breast

## Primary outcomes

### 1

#### Description

incidence of drug related adverse effects

#### Timepoint

after each 3 weeks period of recieving chemotherapy  
regimen

#### Method of measurement

physical examination

### 2

#### Description

information about all adwers drug reaction, adverse  
effects and clinical information

#### Timepoint

after each 3 weeks period of recieving chemotherapy  
regimen and exactly befor recieving next regimen

#### Method of measurement

physical examination

## Secondary outcomes

### 1

#### Description

blood tests include: hemoglobin, Diff and total RBC, WBC  
and platelets count, liver function tests include ALT, AST,

bilirubin and alkaline phosphatase

**Timepoint**

after each 3 weeks period of receiving chemotherapy regimen

**Method of measurement**

blood test

**2**

**Description**

assessment of cardiac arrhythmia

**Timepoint**

after each 3 weeks period of receiving chemotherapy regimen

**Method of measurement**

electrocardiography

**3**

**Description**

Assessment of Left Ventricular Ejection Fraction

**Timepoint**

after each 3 weeks period of receiving chemotherapy regimen

**Method of measurement**

echocardiography

**4**

**Description**

ECOG grade

**Timepoint**

after each 3 weeks period of receiving chemotherapy regimen

**Method of measurement**

physical examination

**Intervention groups**

**1**

**Description**

Patients in control group at first will receive Docetaxel (100mg/m<sup>2</sup>) in days 1,22 and 43. also infusion of Roche trastuzumab (Herceptin) (4mg/kg) as loading dose and 2mg/kg in days 8, 15, 22, 29, 36, 43, 50 and 57 via IV route. after that in 3 periods with 3 weeks interval we will infuse 5FU 600mg/m<sup>2</sup>, Cyclophosphamide 600mg/m<sup>2</sup> and Epirubicin 60mg/m<sup>2</sup> at first day of each interval.

**Category**

Treatment - Drugs

**2**

**Description**

Patients in intervention group at first will receive Docetaxel (100mg/m<sup>2</sup>) in days 1,22 and 43. also infusion of AryoGen trastuzumab (Hercease) (4mg/kg) as loading dose and 2mg/kg in days 8, 15, 22, 29, 36, 43, 50 and 57 via IV route. after that in 3 periods with 3 weeks interval we will infuse 5FU 600mg/m<sup>2</sup>, Cyclophosphamide 600mg/m<sup>2</sup> and Epirubicin 60mg/m<sup>2</sup> at first day of each interval.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Jahad daneshgahi center

**Full name of responsible person**

Safa Najjar Najafi

**Street address**

Molla sadra street, Tehran, Iran

**City**

Tehran

**2**

**Recruitment center**

**Name of recruitment center**

Firozgar Hospital

**Full name of responsible person**

Mohsen Razavi

**Street address**

Valiasr Street, Valadi Street, Tehran, Iran

**City**

Tehran

**3**

**Recruitment center**

**Name of recruitment center**

Emam khomini Hospital

**Full name of responsible person**

Seyed Reza Safaeinodehi, Farhad Shahi, Sanambar Sadighi, Mohammad Esfandbod, Seyed Amir Hossein Emam

**Street address**

Keshavarz Blvd., Tehran, Iran

**City**

Tehran

**4**

**Recruitment center**

**Name of recruitment center**

501 Artesh Hospital

**Full name of responsible person**

Mohsen Rajaeinejad

**Street address**

Etemadzadeh St.,Dr.Fatemi Ave. 10000 Tehran Iran

**City**

Tehran

**5**

**Recruitment center**

**Name of recruitment center**

Booali Hospital

**Full name of responsible person**

Arash Jenabian

**Street address**

Imam Hossein Square, Beginning Damavand Avenue,  
Tehran, Iran

**City**

Tehran

**6**

**Recruitment center**

**Name of recruitment center**

Ayatollah Taleghani Hospital

**Full name of responsible person**

Mojtaba Ghadyani

**Street address**

Tabnak St., Velenjak Region, Chamran High Way,  
Tehran, Iran

**City**

Tehran

**7**

**Recruitment center**

**Name of recruitment center**

Mehrad Hospital

**Full name of responsible person**

Jahangir Raafat

**Street address**

Mir Emad St., Tehran, Iran

**City**

Tehran

**8**

**Recruitment center**

**Name of recruitment center**

Masud clinic

**Full name of responsible person**

Masoud Iravani

**Street address**

19th street. Amirabad. Tehran Iran

**City**

Tehran

**9**

**Recruitment center**

**Name of recruitment center**

Toos Hospital

**Full name of responsible person**

Saeed Salimie

**Street address**

Ebadi street, Tehran, Iran

**City**

Tehran

**10**

**Recruitment center**

**Name of recruitment center**

Hazrate Rasool

**Full name of responsible person**

Nafiseh Ansari nejhada

**Street address**

Niyayesh St., Satarkhan St., Tehran, Iran

**City**

Tehran

**11**

**Recruitment center**

**Name of recruitment center**

Alzahra clinic

**Full name of responsible person**

Abbas Hajiqolami

**Street address**

Sheikh mofis St. Alzahra clinic, Isfahan, Iran

**City**

Esfahan

**12**

**Recruitment center**

**Name of recruitment center**

Shafa Hospital

**Full name of responsible person**

Mohammad Seghatoleslami, Mehran Hosseinzadeh,  
Ahmad Ahmad Zadeh

**Street address**

Ahvaz, Khuzestan, Iran

**City**

Ahvaz

**13**

**Recruitment center**

**Name of recruitment center**

Namazi Hospital

**Full name of responsible person**

Mani Ramzi, Alireza Rezvani

**Street address**

Zand Street, Namaz Square, Shiraz, Fars, Iran

**City**

Shiraz

**14**

**Recruitment center**

**Name of recruitment center**

Shahid faqihi Hospital

**Full name of responsible person**

Shirin Haqiqat joo

**Street address**

Fars Province, Shiraz, District 6, Chamran Blvd

**City**

Shiraz

**15**

**Recruitment center**

**Name of recruitment center**

Bahonar Hospital

**Full name of responsible person**

Bahjat Kalantari, Vahid Moazed

**Street address**

Kerman street century martyr, Kerman, Iran

**City**

Kerman

## 16

### Recruitment center

**Name of recruitment center**

Ayatollah Taleghani Hospital

**Full name of responsible person**

Mehrdad Payandeh

**Street address**

Martyr Beheshti Blvd., Kermanshah, Iran

**City**

Kermanshah

## 17

### Recruitment center

**Name of recruitment center**

Emam Reza Hospital

**Full name of responsible person**

Abolghasem Allahyari

**Street address**

Emam Reza Square, Ebne Sina Avenue, Mashhad, Iran

**City**

Mashhad

## 18

### Recruitment center

**Name of recruitment center**

Seyedshohada Hospital

**Full name of responsible person**

Mohammad Reza Mortazavi Zade

**Street address**

Imam St., Yazd

**City**

Yazd

## 19

### Recruitment center

**Name of recruitment center**

Razi Hospital

**Full name of responsible person**

Behrooz Najafi, Siroos Qarib, Hossein Mirpoor

**Street address**

Sardar jangal, Rasht, Iran

**City**

Rasht

## 20

### Recruitment center

**Name of recruitment center**

Hazrate Rasool

**Full name of responsible person**

Mahdi Mirbolouk

**Street address**

Imam khomeinim Blvd, Rasht, Iran

**City**

Rasht

## 21

### Recruitment center

**Name of recruitment center**

Al iebn Abitaleb Hospital

**Full name of responsible person**

Mahdi Hashemi

**Street address**

Dr. hesabi sq. Salamat Blvd, Zahedan, Iran

**City**

Zahedan

## 22

### Recruitment center

**Name of recruitment center**

Tohid Hospital

**Full name of responsible person**

Bayazid Qaderi

**Street address**

Pataran Ave., Sanandaj, Iran

**City**

Sanandaj

## 23

### Recruitment center

**Name of recruitment center**

Immam Khomeini Hospital

**Full name of responsible person**

Abolqasem Janbabaie, Ramin Shekarriz, Mohammad islami, Ehsan Zaboli

**Street address**

Imam Ave., Jooybar Blvd, Sari, Iran

**City**

Sari

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Aryogene pharmed company

**Full name of responsible person**

Somayeh Amini

**Street address**

Orchid Pharmed No 2, Khorasani deadend, Derakhti St, Dadman St, Shahrak-eGharb

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Aryogene pharmed company

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**  
**Type of organization providing the funding**  
*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Orchid Pharmed Company  
**Full name of responsible person**  
Ramin Azhdarazadeh  
**Position**  
Pharmacist (PharmD), Clinical Trial Manager  
**Other areas of specialty/work**  
**Street address**  
No 10, Ninth street, Iranzamin Blvd, Shahrak-e-Gharb  
**City**  
Tehran  
**Postal code**  
1465884171  
**Phone**  
+98 21 8808 8821  
**Fax**  
**Email**  
No.2, khorasani Alley, Derakhti Ave, dadman blvd,  
Shahrak-e-Gharb Tehran Tehran Iran, Islamic Rep  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
jihad-e-daneshgahi breast cancer institute  
**Full name of responsible person**  
Dr keivan majidzadeh  
**Position**  
PHD of medical biotechnology  
**Other areas of specialty/work**  
**Street address**  
NO45- west shahid nazari st- aboureyhan st-  
enghelab e eslami st  
**City**  
tehran  
**Postal code**  
1315893111

**Phone**  
+98 21 6648 0877  
**Fax**  
+98 21 6695 2040  
**Email**  
kmajidzadeh@tums.ac.ir  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Orchid Pharmed Company  
**Full name of responsible person**  
Somayeh Amini  
**Position**  
Pharmacist (PharmD), Medical Manager  
**Other areas of specialty/work**  
**Street address**  
No 10, Ninth street, Iranzamin Blvd, Shahrak-e-Gharb  
**City**  
tehran  
**Postal code**  
1465884171  
**Phone**  
+98 21 8807 5724  
**Fax**  
**Email**  
amini.s@orchidpharmed.com  
**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
*empty*  
**Study Protocol**  
*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**  
*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*