Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 recieve 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)

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
IR.ACECR.IBCRC.REC.1394.3

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 advers 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 recieving chemotherapy regimen

Method of measurement

blood test

2

Description

assessment of cardiac arrhythmia

Timepoint

after each 3 weeks period of recieving chemotherapy regimen

Method of measurement

electrocardiography

3

Description

Assessment of Left Ventricular Ejection Fraction

Timepoint

after each 3 weeks period of recieving chemotherapy regimen

Method of measurement

echocardiography

4

Description

ECOG grade

Timepoint

after each 3 weeks period of recieving chemotherapy regimen

Method of measurement

physical examination

Intervention groups

1

Description

Patients in control group at first will receive Docetaxel (100mg/m2) 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/m2, Cyclophosphamide 600mg/m2 and Epirubicin 60mg/m2 at first day of each interval.

Category

Treatment - Drugs

2

Description

Patients in intervention group at first will receive Docetaxel (100mg/m2) 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/m2, Cyclophosphamide 600mg/m2 and Epirubicin 60mg/m2 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 nejhad

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

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1465884171

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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

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

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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

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Postal code

1465884171

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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