Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Aug 2026

Double blind، Randomized clinical trial of the efficacy of Aryogen Trastuzumab compared to Genentech/roche Trastuzumab in breast cancer

Protocol summary

Summary

The objective of this randomized, double blind trial is to compare the efficacy of Herceptinl® and trastusumab is manufactured by Aryogen (HerZux) in neoadjuvant chemotherapy on the patients with breast cancer.In this study, 120 patients with HER2 positive breast cancer who meet the inclusion/exclusion criteria will be recruited and randomly assigned into two intervention or a control group. The patients in the intervention group will receive trastuzumab(Aryogen) and in the control group will receive Herceptin® as same dosage and form.Pathological response of breast cancer will be measured after the intervention and compared between the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208116302N4**
Registration date: **2013-03-16, 1391/12/26**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-03-16, 1391/12/26

Registrant information

Name
Kamran Kamyar
Name of organization / entity
AryoGen Biopharma Company
Country
Iran (Islamic Republic of)
Phone
00982616102587،00982616101568
Email address
kamyark@aryogen.com

Recruitment status

Recruitment complete

Funding source

AryoGen Biopharma company

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2013-10-23, 1392/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Double blind، Randomized clinical trial of the efficacy of Aryogen Trastuzumab compared to Genentech/roche Trastuzumab in breast cancer

Public title

Comparative analysis of trastuzumab(Aryogen) with Herceptin®

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:older than 18 years; HER2 positive (3+) in IHC test or (2+) with positive FISH test; size of tumor more than 2cm; ECOG grade between 0-1; LVEF more than 55%; complete inform consent form Exclusion criteria:metastatic breast cancer; bilaterally breast cancer; other neoplasms; bone marrow failure; renal failure; liver failure; heart failure; uncontroled hypertension; pregnancy during study or planning for pregnancy at the beginning of study. .

Age

From **18 years** old to **80 years** old

Gender

Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
research center of new technologies in biological science- Ibne Sina
Street address
No.65,cross ravanmehr street, abureyhan street,enghelab avenue
City
tehran
Postal code
Approval date
2012-06-12, 1391/03/23
Ethics committee reference number
15/882/91/ص

Health conditions studied

1

Description of health condition studied
breast cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
pathological response of breast tumor according to sataloff criteria
Timepoint
18 weeks after beginning of neoadjuvant therapy
Method of measurement
pathological evaluation of breast biopsy by pathologist

Secondary outcomes

1

Description
Amplitude of probable hematologic side effects
Timepoint
once weekly after beginning of neoadjuvant therapy
Method of measurement
by laboratory tests

2

Description
Amplitude of probable fever side effect
Timepoint
once weekly after beginning of neoadjuvant therapy
Method of measurement
clinical,by phisician

3

Description
Amplitude of probable gastrointestinal side effects
Timepoint
once weekly after beginning of neoadjuvant therapy
Method of measurement
clinical and by laboratory tests

4

Description
Amplitude of probable Pulmonary side effects
Timepoint
once weekly after beginning of neoadjuvant therapy
Method of measurement
clinical,by phisician

5

Description
Amplitude of probable Cardiac side effects
Timepoint
once weekly after beginning of neoadjuvant therapy
Method of measurement
clinical,by phisician

6

Description
Amplitude of probable renal side effects
Timepoint
once weekly after beginning of neoadjuvant therapy
Method of measurement
clinical and by laboratory tests

7

Description
Amplitude of probable neurologic side effects
Timepoint

once weekly after beginning of neoadjuvant therapy

Method of measurement

clinical,by phisician

8

Description

Amplitude of probable allergic side effects

Timepoint

once weekly after beginning of neoadjuvant therapy

Method of measurement

clinical,by phisician

Intervention groups

1

Description

in interventional group:at first course of therapy:1-carboplatin 150mg(AUC>6) 2- docetaxel 75mg/kg 3-Trastuzumab (Aryogen) 8mg/kg. at next 5 course of therapy the same medicines are used but only Trastuzumab dose is 6mg/kg. intervals between courses of therapy are 3 weeks.

Category

Treatment - Drugs

2

Description

in control group:at first course of therapy: 1-carboplatin 150mg(AUC>6) 2- docetaxel 75mg/kg 3- Trastuzumab (Herceptin) 8mg/kg. at next 5 course of therapy the same medicines are used but only Herceptin dose is 6mg/kg. intervals between courses of therapy are 3 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Research center of new technologies in biological science- Ibne Sina

Full name of responsible person

Dr. Keyvan Majidzadeh

Street address

No.65, cross ravanmehr street, abureyhan street,enghelab avenue

City

tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

AryoGen Biopharma Company

Full name of responsible person

Dr. Behrouz Vaziri, general manager

Street address

Cross Tajbakhsh Street, 24th Kilometer Makhsous, Tehran - Iran .

City

Garmdareh

Grant name

Grant code / Reference number

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

Yes

Title of funding source

AryoGen Biopharma 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

AryoGen Biopharma Company

Full name of responsible person

Dr.Kamran Kamyar

Position

General Practitioner/ Medical Manager

Other areas of specialty/work

Street address

Cross Tajbakhsh Street, 24th Kilometer Makhsous, Tehran - Iran

City

Garmdareh

Postal code

Phone

+98 26 3610 4644

Fax

Email

kamyark@aryogen.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Keyvan Majidzadeh

Position

Medical Doctor,Biotechnological PHD

Other areas of specialty/work

Street address

No.65, cross ravanmehr street, abureyhan

street,enghelab avenue

City

tehran

Postal code

Phone

+98 21 6648 8980

Fax

Email

kmajidzadeh@razi.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

AryoGen Biopharma Company

Full name of responsible person

Dr.Kamran Kamyar

Position

General Practitioner/ Medical Manager

Other areas of specialty/work

Street address

Cross Tajbakhsh Street, 24th Kilometer Makhsous, Tehran - Iran

City

Garmdareh

Postal code

Phone

00

Fax

Email

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