

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Oct 2026

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

Protocol summary

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Summary

The objective of this randomized, double blind trial is to compare the efficacy of Herceptin® and trastuzumab 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.

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

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

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 informed consent form
Exclusion criteria: metastatic breast cancer; bilaterally breast cancer; other neoplasms; bone marrow failure; renal failure; liver failure; heart failure; uncontrolled 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

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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

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00

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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

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

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Tehran - Iran