

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The efficiency of endoradiotherapy with ¹⁷⁷Lu-Trastuzumab in patients with resistant or relapsed HER2-positive breast cancer

Protocol summary

Study aim

The efficiency of endoradiotherapy with ¹⁷⁷Lu-Trastuzumab in patients with resistant or relapsed HER2-positive breast cancer

Design

This is an interventional clinical trial with a single group design of 15 patients, performing between January 2022 and June 2023 that will be followed between treatment sessions.

Settings and conduct

Patients are selected and justified in the nuclear medicine center of the Persian Gulf hospital at Bushehr. The consent form is obtained and finally, the treatment will be performed with intravenous injection of ¹⁷⁷Lu-Trastuzumab. After injection, patients will be undergone a whole-body scan for the assessment of radiotracer distribution. Six to eight weeks after the ¹⁷⁷Lu-Trastuzumab therapy, the patients will be visited by oncologists and nuclear medicine physicians and if there was not any toxicity, the next treatment session will be performed

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age ≥ 18 years, Patients with confirmed HER2+ metastatic breast cancer using ⁶⁸Ga-Trastuzumab PET/CT, Eastern Cooperative Oncology Group Performance Status (ECOG) ≤ 2 , Having hematologic parameters as: (i) Absolute neutrophil count ≥ 1000 cells/mm³; (ii) Platelet count $\geq 100,000$ /mm³; (iii) Hemoglobin ≥ 9 g/dL Signed informed consent. Exclusion criteria: Pregnancy, Inability to provide written informed consent, Patients with known sensitivity or contraindication to Herceptin, Patients who had an active, uncontrolled bacterial, viral, or fungal infection(s) requiring systemic therapy.

Intervention groups

We are going to use a single group of patients to evaluate the efficiency of ¹⁷⁷Lu-Trastuzumab in the treatment of HER2-positive breast cancer.

Main outcome variables

The proportion of patients who have a partial, stable (not-progressed), or complete response to therapy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210612051548N3**

Registration date: **2021-10-18, 1400/07/26**

Registration timing: **prospective**

Last update: **2021-10-18, 1400/07/26**

Update count: **0**

Registration date

2021-10-18, 1400/07/26

Registrant information

Name

Majid Assadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 77 3332 0361

Email address

assadipoya@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2023-06-21, 1402/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficiency of endoradiotherapy with ¹⁷⁷Lu-Trastuzumab in patients with resistant or relapsed HER2-positive breast cancer

Public title

Endoradiotherapy with ¹⁷⁷Lu-Trastuzumab in patients with HER2-positive breast cancer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age ≥18 years Patients with confirmed HER2-positive breast cancer using ⁶⁸Ga-Trastuzumab PET/CT Eastern Cooperative Oncology Group Performance Status (ECOG) ≤ 2 Having hematologic parameters as: (i) Absolute neutrophil count ≥ 1000 cells/mm³; (ii) Platelet count ≥ 100,000/mm³; (iii) Hemoglobin ≥ 9 g/dL Signed informed consent form

Exclusion criteria:

Pregnant woman Inability to provide written informed consent. Patients with known sensitivity or contraindication to Herceptin. The patient had an active, uncontrolled bacterial, viral, or fungal infection(s) requiring systemic therapy. Patients have psychiatric illness/social situations that would interfere with compliance with study requirements

Age

From **18 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **15**

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

Research Ethics Committees of Bushehr province university of medical sciences

Street address

Bushehr University of Medical Science, Moallem Street, Bushehr, Iran

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Bushehr

Province

Boushehr

Postal code

45654775

Approval date

2021-06-27, 1400/04/06

Ethics committee reference number

IR.BPUMS.REC.1400.053

Health conditions studied**1****Description of health condition studied**

Malignant breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes**1****Description**

Numbe of treated breast cancer patients

Timepoint

4-6 weeks after last treatment session

Method of measurement

Image-based response using ⁶⁸Ga-Trastuzumab PET/CT

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In this study, the ¹⁷⁷Lu-Trastuzumab PET/CT radiopharmaceutical is injected intravenously into 15 patients with breast cancers according to the ⁶⁸Ga-Trastuzumab PET/CT. Then whole-body scan is performed at 24 hours, and 48 hours after injection to assess radiotracer distribution. Six to eight weeks after the ¹⁷⁷Lu-Trastuzumab PET/CT therapy, the patients will be visited by oncologists and nuclear medicine physicians and if there was not any toxicity, the next treatment session will be performed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Nuclear Medicine Center, Persian Gulf Hospital

Full name of responsible person

Majid Assadi

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Persian Gulf Hospital, Taleghani Street, Bushehr, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Gholamreza Khamisipour

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Vice-Chancellor for Research and Technology of
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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Boushehr University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

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

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Boushehr University of Medical Sciences

Full name of responsible person

Majid Assadi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Nuclear Medicine

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Research Instructor

Latest degree

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Other areas of specialty/work

Medical Physics

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available