

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A clinical trial of a diagnostic radiopharmaceutical (⁶⁴Cu-DOTA-Trastuzumab) in patients with metastatic breast cancer and HER2-positive

Protocol summary

Study aim

1.Introduction of a new imaging technique for HER2-positive metastatic lesions of breast cancer using trastuzumab-labeled radiopharmaceutical. 2.Presentation a future treatment of HER2-positive metastatic breast cancer lesions with beta-emitting radiopharmaceuticals.

Design

Patients in a group of 22 are randomly injected with a radiopharmaceutical and then imaged.

Settings and conduct

The radiopharmaceutical is produced by Pars Isotope Company. Patients are selected and justified in the oncology clinic or the office of Professor Amir Hossein Emami, and if they wish, they are referred to the nuclear medicine center of Imam Khomeini Hospital. In the nuclear medicine center of Imam Khomeini Hospital, a consent form is obtained and then an injection is conducted and finally, imaging is performed.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patient with metastatic breast cancer and HER2 receptor Over 18 years old Stage 4 No previous treatment with Herceptin Negative estrogen and progesterone receptors Exclusion Criteria: Pregnant patients Patients who do not have appropriate heart function

Intervention groups

Imaging is performed after the injection of 10 to 13 mcg of copper 64 (radioactive material) labeled trastuzumab.

Main outcome variables

Uptake of copper 64 labeled trastuzumab within known metastatic lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180818040823N2**

Registration date: **2020-12-23, 1399/10/03**

Registration timing: **prospective**

Last update: **2020-12-23, 1399/10/03**

Update count: **0**

Registration date

2020-12-23, 1399/10/03

Registrant information

Name

Mehrshad Abbasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2405

Email address

meabbasi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial of a diagnostic radiopharmaceutical (⁶⁴Cu-DOTA-Trastuzumab) in patients with metastatic breast cancer and HER2-positive

Public title

Application of labeled trastuzumab to diagnose breast cancer in HER2 positive cases

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with metastatic breast cancer and HER2 receptor stage 4 No previous treatment with Herceptin Negative estrogen and progesterone receptors

Exclusion criteria:

Age

From 18 years old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 22

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

Tehran University of Medical Science

Street address

Research office, 1st floor, block NO1 of medical science faculty, Poorsina St , Qods St, Enghelab Sq.

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2020-01-14, 1398/10/24

Ethics committee reference number

IR.TUMS.MEDICINE.REC.98.758

Health conditions studied

1

Description of health condition studied

Metastatic breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Uptake of radiopharmaceutical in lesions

Timepoint

At imaging time (60 minutes after injection)

Method of measurement

Observation and semi-quantification using SUV

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, 5 mg of ⁶⁴Cu-DOTA-trastuzumab radiopharmaceutical with a dose of 500-300 MB / h MBq, is injected into 22 patients with metastatic breast cancer and HER2 receptor. Then PET imaging is performed in 3 intervals, 1 h, 24 h day, and 48 h after injection. The drug is supplied by Pars Isotope Company.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Mehrshad Abbasi

Street address

Nuclear Medicine Department, Imam Khomeini Hospital Complex, Dr. Qarib street, Keshavarz boulevard

City

Tehran

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meabbasi@tums.ac.ir

Web page address

2

Recruitment center

Name of recruitment center

Cancer Institute, Imam Khomeini Hospital Complex

Full name of responsible person

Amirhosein Emami

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Cancer Institute, Imam Khomeini Hospital Complex,
Dr. Qarib street, Keshavarz boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohamadali Sahraiyan

Street address

Vice-Chancellor for Research and Technology, sixth
floor, Central University Organization, Quds Street,
Keshavarz Boulevard

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msahrai@sina.tums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mehrshad Abbasi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Nuclear Medicine

Street address

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Person responsible for scientific inquiries

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Position

Associated Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The sharable data are de-identified images of patients
with this new diagnostic method and performed
quantitative and qualitative analyzes

When the data will become available and for how long

The access period will start 6 months after the results
are published

To whom data/document is available

Both academics and non-faculty medical staff will be able
to use it.

Under which criteria data/document could be used

The de-identified images of the patients will be available
by email to the principal investigator and can be applied
by those who need access.

From where data/document is obtainable

For more images and data than what has been published
as an article, applicants can contact the principal
researcher via email.

What processes are involved for a request to access data/document

An initial response will be given up to 24 hours later after
sending the email, and according to the type of applied
information, the applicant will be provided with the
applied data for up to 1 month.

Comments