

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Clinical evaluation of 68Ga-SSSLTVSPWY peptide for evaluation of HER2 overexpression status in patients with breast cancer with PET/CT and compare to 18FDG

Protocol summary

Study aim

Diagnosis and determination of HER2 status in primary and metastatic lesions in breast cancer

Design

Ten non-randomized breast cancer patients confirmed by the inclusion criteria will be considered for a phase I clinical study by HER2 spot and whole-body imaging.

Settings and conduct

The SSSLTVSPWY peptide was labeled with gallium-68 to determine HER2 status for subsequent treatment plans in breast cancer patients. The study site is Khatam Hospital in Tehran, and PET imaging is performed after radiopeptide injection. The study is not blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female patients with HER2-overexpressed breast tumors (primary or metastatic mass) after screening with an IHC test (with 3+ result) or FISH test; Exclusion criteria: Pregnancy, Breastfeeding, uncontrolled kidney, and liver disorders, and history of allergy to radiopharmaceuticals

Intervention groups

The intervention group includes patients with HER2-positive breast cancer. A peptidic kit (Schafer-N Company (Denmark)) would be labeled with gallium-68 (Parsisotope) in the nuclear medicine department of Khatam Al-Anbiya hospital, and a single dose of 20 µg would be injected intravenously into the patients. Imaging would be performed using positron emission tomography (PET) and the results would ultimately compare with standard radiopharmaceutical 18FDG.

Main outcome variables

Maximum standardized uptake value (SUVmax) by tumor; Ratio of tumor radioactivity to breast glandular tissue; Specificity; Sensitivity; Dosimetry; Positive and negative predictive value; Localization of tumor;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230312057691N1**

Registration date: **2023-04-10, 1402/01/21**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-10, 1402/01/21**

Update count: **0**

Registration date

2023-04-10, 1402/01/21

Registrant information

Name

Fatemeh Ebrahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical evaluation of 68Ga-SSSLTVSPWY peptide for evaluation of HER2 overexpression status in patients with breast cancer with PET/CT and compare to 18FDG

Public title

Clinical evaluation of the SSSLTVSPWY peptide labeled with 68Ga

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with HER2-overexpressed breast tumors (primary or metastatic mass) after screening with IHC test (with 3+ result) or FISH test

Exclusion criteria:

Pregnancy Breastfeeding Uncontrolled kidney and liver disorders A history of allergy to radiopharmaceuticals

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 25

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**

The ethics committee of Mazandaran University of Medical Sciences

Street address

Beginning of Valiasr Highway, Three Way Jouybar,

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Sari

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Mazandaran

Postal code

33971-48157

Approval date

2023-03-14, 1401/12/23

Ethics committee reference number

IR.MAZUMS.REC.1401.551

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

Breast cancer

ICD-10 code

C50.91

ICD-10 code description

Malignant neoplasm of breast of unspecified site, female

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

Maximum standardized uptake value (SUVmax) radioactivity by tumor

Timepoint

Imaging of the breast at 0.5,1,2 and 4 hours after the administration of the radiotracer

Method of measurement

PET/CT imaging

2**Description**

Ratio of tumor radioactivity to breast glandular tissue

Timepoint

Imaging of the breast at 0.5,1,2 and 4 hours after the administration of the radiotracer

Method of measurement

PET/CT imaging

3**Description**

Specificity

Timepoint

Imaging of the breast at 0.5,1,2 and 4 hours after the administration of the radiotracer

Method of measurement

PET/CT imaging

4**Description**

Sensitivity

Timepoint

Imaging of the breast at 0.5,1,2 and 4 hours after the administration of the radiotracer

Method of measurement

PET/CT imaging

5**Description**

Dosimetry

Timepoint

Imaging of the breast at 0.5,1,2 and 4 hours after the administration of the radiotracer

Method of measurement

PET/CT imaging

6

Description

Positive and negative predictive value

Timepoint

Imaging of the breast at 0.5,1,2 and 4 hours after the administration of the radiotracer

Method of measurement

PET/CT imaging

7

Description

Localization of tumor

Timepoint

Imaging of the breast at 0.5,1,2 and 4 hours after the administration of the radiotracer

Method of measurement

PET/CT imaging

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group includes patients with HER2-positive breast cancer. This evaluation is a diagnostic method using the positron emission tomography (PET) modality, in which the labeled peptide radiopharmaceutical with gallium-68 (Parsisotope) is prescribed to patients in a single dose of 20 µg. A Danish company (Schafer-N Company (Denmark)) would prepare the mentioned peptide and there is a chemical analysis that confirms its purity. The intended radiopharmaceutical is labeled and formulated in Khatam Al-Anbiya hospital, Tehran, and the radiochemical quality and purity would be checked and confirmed before administration to the patient. Radiolabelled medicine, would be injected in a single dose intravenously. The place of injection is in the nuclear medicine department of Khatam Al-Anbiya hospital, where there is necessary medical equipment and a doctor in case the patient suffers complications from the injection, for the prevention and treatment of the patients. The results would ultimately compare with standard radiopharmaceutical 18FDG.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam Al-Anbiya Hospital

Full name of responsible person

Dr. Mahdi Akhlaghi

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Rashid Yasemi Street, Upper than Mirdamad St., Vali-Asr St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Pedram Ebrahimnejad

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Moalem Square, Moalem Street, Ayatollah Taleghani Blvd

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Dr. Mahdi Akhlaghi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nuclear Pharmacy

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Person responsible for updating data

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Other areas of specialty/work

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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