Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 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

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Fatemeh Ebrahimi

Name of organization / entity

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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,

City
Sari

Province
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 scientific inquiries

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Mazandaran University of Medical Sciences

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Person responsible for updating data

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Non-faculty specialist

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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