

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Clinical evaluation of the SSSLTVPWY peptide labeled with 99m TC to determine HER2 status for the treatment of patients with Breast Cancer

Protocol summary

Study aim

Diagnostic, Determination of HER2 status in primary and metastatic lesions in Breast Cancer

Design

20 patients with breast cancer who filled the inclusion criteria and accept to precipitate in this study initially designed for HER 2 imaging in spot and whole body and also SPECT modes and then referred for breast lesion biopsy to determination of HER2 status by Immunohistochemistry and other conventional diagnostic testes as law. In the end of study we compared the provided images with Immunohistochemistry result as a gold standard to determine the specificity, sensitivity, negative predictive value, positive predictive value and accuracy of test.

Settings and conduct

The SSSLTVPWY peptide labeled with 99mTc to determine HER2 status for the treatment of patients with Breast Cancer; The site of the study is Fatemeh Al zahra hospital in Sari, after the injection of Radiopeptide the imaging in point and total body, as well as the SPECT mode, is performed and the images are matched with the results of the immunohistochemistry method. This study is not blinded.

Participants/Inclusion and exclusion criteria

Inclusion:Female; Primary breast cancer; Size greater than 2cm; Without any history of biopsy Exclusion:Renal failure; Liver dysfunction; Pregnancy; Lactation

Intervention groups

This is a preliminary diagnostic study for imaging of HER2 positive breast cancer by a newly designed radio-peptide

Main outcome variables

Radiotracer uptake by breast cancer; Distribution of radiopeptide in other tissues; Specificity; Sensitivity; Negative predictive value; Positive predictive value; Accuracy

General information

Reason for update

For pharmacokinetic and dosimetry studies, the number of samples needs to be changed from 20 to 25.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180310039019N1**

Registration date: **2018-03-21, 1397/01/01**

Registration timing: **prospective**

Last update: **2019-12-19, 1398/09/28**

Update count: **2**

Registration date

2018-03-21, 1397/01/01

Registrant information

Name

Javad Biabani ardakani

Name of organization / entity

The University of mazandaran

Country

Iran (Islamic Republic of)

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+98 11 3368 5510

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical evaluation of the SSSLTVPWY peptide labeled with 99m TC to determine HER2 status for the treatment of patients with Breast Cancer

Public title

Clinical evaluation of the SSSLTVPWY peptide labeled with 99m TC

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Female Primary breast cancer Size greater than 2cm
Without any history of biopsy

Exclusion criteria:

Renal failure Liver dysfunction Pregnancy Lactation

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

Ethics committee of Mazandaran University of Medical Sciences

Street address

Three Way Jouybar, Beginning of Valiasr Highway

City

Sari

Province

Mazandaran

Postal code

۳۳۹۷۱-۴۸۱۵۷

Approval date

2018-03-06, 1396/12/15

Ethics committee reference number

IR.MAZUMS..REC.1396.1155

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

Radiotracer uptake by breast cancer

Timepoint

Imaging of the breast at 1,2,3 and 4 hours after the administration of the Radiopeptide

Method of measurement

With imaging

Secondary outcomes

1

Description

Distribution of radiopeptide in other tissues

Timepoint

Imaging at 1,2,3 and 4 hours after the administration of the radiopeptide

Method of measurement

With imaging

Intervention groups

1

Description

Intervention group: imaging at 1,2,3 and 4 hours after the intravenous injection of 740 MBq of radiopeptide

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Al Zahra Hospital

Full name of responsible person

Dr. Seyed Mohammad Abedi

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Army Blvd., Imam Hossein Square

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Sponsors / Funding sources

1

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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
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Position

Associate Professor
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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