Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 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

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Iran (Islamic Republic of)

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+98 11 3368 5510

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javadbiabani@ssu.ac.ir

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
Street address
Army Blvd., Imam Hossein Square
City
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Sponsors / Funding sources

1

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Name of organization / entity
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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
Mazandaran University of Medical Sciences
Full name of responsible person
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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