Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The efficacy of radioimmunotherapy with 177Lu-DOTA-RITUXIMAB in refractory or relapsing follicular, mantle cell, and other indolent B-cell lymphomas

Protocol summary

Study aim
Evaluate the efficiency of 177Lu-DOTA-RITUXIMAB in CD20-positive B-cell lymphoma patients.

Design
This is an interventional clinical trial with a single group design of 10 patients, performing between December 2021 and March 2023 that will be followed between treatment sessions.

Settings and conduct
Patients will be selected and justified in the nuclear medicine center of the Persian Gulf hospital at Bushehr. The consent form is obtained and finally, the treatment will be performed with intravenous injection of 177Lu-DOTA-RITUXIMAB. Eight to twelve weeks after therapy, the patients will be restaged using 18F-FDG PET/CT. Physical examination, performance status, blood chemistry, hematology, and urine analysis were recorded at baseline. Blood tests will be performed weekly up to week 10 or until recovery from nadir.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Histologically confirmed relapsed or refractory CD20-positive B-cell lymphoma, age greater than 18 years, life expectancy more than 3 months, not pregnant or lactating women, performance status of 2 or better, having appropriate hematological parameters, and signed informed consent form. Exclusion criteria: Patients who had previously undergone radiation therapy to the pelvis, femora, or lumbar spine or high-dose treatment with stem cell transplantation.

Intervention groups
We are going to use a single group of 10 patients to evaluate the efficiency of 177Lu-DOTA-RITUXIMAB in the treatment of CD20-positive B-cell lymphoma patients.

Main outcome variables
Clinical response to 177Lu-DOTA-RITUXIMAB, Number of Patients With Dose Limiting Toxicity (DLT); Cumulative Maximum Tolerated Dose (MTD) and/or Recommended Phase II Dose

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210612051548N4**
Registration date: **2021-11-28, 1400/09/07**
Registration timing: **prospective**

Last update: **2021-11-28, 1400/09/07**
Update count: **0**

Registration date
2021-11-28, 1400/09/07

Registrant information

Name
Majid Assadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 77 3332 0361

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2023-03-20, 1401/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The efficacy of radioimmunotherapy with 177Lu-DOTA-RITUXIMAB in refractory or relapsing follicular, mantle cell, and other indolent B-cell lymphomas

Public title
Radioimmunotherapy with 177Lu-DOTA-RITUXIMAB in B-cell lymphoma

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Histologically confirmed relapsed or refractory CD20-positive B-cell lymphoma Age greater than 18 years Life expectancy more than 3 months Notpregnant or lactating women Performance status of 2 or better according to the World Health Organization scale. Absolute neutrophil count above1.5 × 109/L, a circulating lymphocyte count below 5 × 109/L, a platelet count above 100 · 109/L, a total bilirubin level of no more than 20 mmol/L, an alanine aminotransferase level below 2.5 times normal, and a serum creatinine clearance level above 60 mL/min. Signed informed consent form

Exclusion criteria:
Patients who had previously undergone radiation therapy to the pelvis, femora, or lumbar spine or high-dose treatment with stem cell transplantation.

Age
From **18 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **10**

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
Research Ethics Committees of Bushehr province university of medical sciences

Street address
Bushehr University of Medical Science, Moallem Street, Bushehr, Iran

City
Bushehr

Province
Boushehr

Postal code
45654775

Approval date
2019-03-04, 1397/12/13

Ethics committee reference number
IR.BPUMS.REC.1397.124

Health conditions studied

1

Description of health condition studied
CD20-positive B-cell Lymphoma

ICD-10 code
C83.0

ICD-10 code description
Small cell B-cell lymphoma

Primary outcomes

1

Description
Number of patients with toxicity

Timepoint
weekly up to week 10 or until recovery from nadir

Method of measurement
Blood chemistry, hematology, and urine analysis

2

Description
The proportion of patients who have a partial, stable (not-progressed), or complete response to therapy.

Timepoint
8-12 weeks after treatment

Method of measurement
18F-FDG PET/CT

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: In this study, the 177Lu-DOTA-RITUXIMAB PET/CT radiopharmaceutical will be injected intravenously into 10 patients with lymphoma according to the 18F-FDG PET/CT. Eight to twelve weeks after therapy, the patients will be restaged

using 18F-FDG PET/CT. Physical examination, performance status, blood chemistry, hematology, and urine analysis were recorded at baseline. Blood tests will be performed weekly up to week 10 or until recovery from nadir.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Nuclear Medicine Center, Persian Gulf Hospital
Full name of responsible person
Majid Assadi
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Persian Gulf Hospital, Taleghani Street, Bushehr, Iran
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Boushehr 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
Boushehr University of Medical Sciences
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Majid Assadi
Position
Professor
Latest degree
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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