

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

##### Study aim

Evaluate the efficiency of <sup>177</sup>Lu-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 <sup>177</sup>Lu-DOTA-RITUXIMAB. Eight to twelve weeks after therapy, the patients will be restaged using <sup>18</sup>F-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 <sup>177</sup>Lu-DOTA-RITUXIMAB in the treatment of CD20-positive B-cell lymphoma patients.

##### Main outcome variables

Clinical response to <sup>177</sup>Lu-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)

##### Phone

+98 77 3332 0361

##### Email address

assadipoya@yahoo.com

##### 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 above  $1.5 \times 10^9/L$ , a circulating lymphocyte count below  $5 \times 10^9/L$ , a platelet count above  $100 \cdot 10^9/L$ , 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**

Boushehr University of Medical Sciences

**Full name of responsible person**

Gholamreza Khamisipour

**Street address**

Vice-Chancellor for Research and Technology of Bushehr University of Medical Sciences, Salman-e-Farsi Blvd, Bushehr, Iran.

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**Fax****Email**

khamisipourgholamreza@gmail.com

**Web page address****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

**Full name of responsible person**

Majid Assadi

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Nuclear Medicine

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Boushehr University of Medical Sciences

**Full name of responsible person**

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**Position**

Professor

**Latest degree**

Specialist

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Boushehr University of Medical Sciences  
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Narges Jokar  
**Position**  
Research Instructor  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Medical Physics  
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The Persian Gulf Nuclear Medicine Research Center,  
Bushehr University of Medical Sciences, Moallem  
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Bushehr  
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Boushehr  
**Postal code**

## 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