

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### A therapeutic and side effects' comparison between Reditux and brand type (MabThera) in Diffuse Large B Cell Lymphoma (DLBCL)

#### Protocol summary

##### Summary

This study will be performed for evaluation of therapeutic as well as side effects of Reditux compared with Mabthera with bio-similar properties. Our hypothesis is that these two drugs have similar efficacy in outcome of Diffuse Large B Cell Lymphoma (DLBCL) patients. This study is a parallel design, randomized double blind clinical trial as well as an equivalence/ non inferiority trial. Patients with diagnosis of DLBCL whose diagnoses were confirmed by CD20 positivity in IHC or flow cytometry will be included. Then, the patients will be entered onto the two arms based on balanced permuted block randomization. Patients in the two arms will be treated with Reditux or Mabthera (375 mg/m<sup>2</sup>) every 3 weeks. Duration of treatment is 6 months (8 courses). Staging is done for all the patients in beginning of treatment. All para-clinical assessments (biochemistry, radiologic, pathologic, radionuclide) will be performed in one center in accordance with uniform standards. A questionnaire will be completed for every patient including demographic data and other information.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201010124920N1**

Registration date: **2011-08-02, 1390/05/11**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2011-08-02, 1390/05/11

##### Registrant information

###### Name

Ramin Heshmat

##### Name of organization / entity

Chronic Diseases Research Center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8822 0086

##### Email address

rheshmat@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Cinnagen Company

##### Expected recruitment start date

2011-08-07, 1390/05/16

##### Expected recruitment end date

2013-08-07, 1392/05/16

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A therapeutic and side effects' comparison between Reditux and brand type (MabThera) in Diffuse Large B Cell Lymphoma (DLBCL)

##### Public title

A Therapeutic and side effects comparison between Reditux and brand tpe (Mabthera) in Diffuse Large B Cell Lymphoma (DLBCL)

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: DLBCL patients 18 to 65 years old (male & female); CD 20 marker positivity; Completion of informal consent. Exclusion criteria: Recurrence DLBCL; Systolic dysfunction (EF<50%); HIV, HBV, HCV markers positivity; History of organ transplantation of other active

malignancy; History of allergy to monoclonal antibodies; ECOG performance status >3; Advanced Liver or renal dysfunctions (Bil T >6 mg/dl or Cr >4 mg/dl).

#### Age

From **18 years** old to **65 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **30**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shahid Beheshti University of Medical Sciences

##### Street address

Vice chancellor for research, Shahid Beheshti  
University of Medical Sciences, Evin, Chamran  
Highway

##### City

Tehran

##### Postal code

198517413

#### Approval date

2011-07-10, 1390/04/19

#### Ethics committee reference number

400/2818

## Health conditions studied

### 1

#### Description of health condition studied

Diffuse large B cell lymphoma (DLBCL)

#### ICD-10 code

C83.3

#### ICD-10 code description

Diffuse non-Hodgkin's lymphoma, Large cell (diffuse)

## Primary outcomes

### 1

#### Description

Radiographic response rate

#### Timepoint

At the end of quarter and end of treatment

#### Method of measurement

Radiography ( CT-Scan/ MRI )

## Secondary outcomes

### 1

#### Description

Hematologic response rate, Partial remission and Complete remission

#### Timepoint

Three weeks (end of treatment), hematologic evaluation is done and the next course of treatment is started. And at the end of the fourth and eighth radiologic evaluation occurs.

#### Method of measurement

The variables measured in blood; through the blood and bone marrow radiological assessment if necessary

## Intervention groups

### 1

#### Description

Mabthera (375 mg/m<sup>2</sup>) every 3 weeks for 6 months (8 courses)

#### Category

Treatment - Drugs

### 2

#### Description

Reditux (375 mg/m<sup>2</sup>) every 3 weeks for 6 months (8 courses)

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Taleghani Hospital

##### Full name of responsible person

Dr. Sina Salari

##### Street address

Evin st.

##### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Cinnagen Company

**Full name of responsible person**

Dr.Ali Bamdad

**Street address**

Fifth Floor, No. 56, Azimi St, Ekbatan Phase 1

**City**

Tehran

**Grant name**

طبق قرارداد ۱۰۲۱۳۷-۸۹ مورخ ۲۰/۱/۱۳۹۰

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Cinnagen Company

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Taleghani Hospital, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Sina Salari

**Position**

Fellowship of Hematology-Oncology

**Other areas of specialty/work**

**Street address**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Taleghani Hospital, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Abbas Haji Fath Ali

**Position**

Associate Professor, Speciality in Hematology

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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**Position**

Fellowship in Hematology-Oncology

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**Web page address**

www.taleghanihospital.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*  
**Clinical Study Report**  
*empty*  
**Analytic Code**

*empty*  
**Data Dictionary**  
*empty*