

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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/m²) 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)

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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/m²) every 3 weeks for 6 months (8
courses)

Category

Treatment - Drugs

2

Description

Reditux (375 mg/m²) 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 ۸۹-۱۰۲۱۳۷ 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

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Other areas of specialty/work

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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