Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy of R-CHOP-21 vs. R-CHOP-14 for untreated stage III and IV B-cell Non-Hodgkin's Lymphoma

Protocol summary

Summary

Aim: The aim of this trial is to evaluate OS, PFS and toxicity of R-CHOP-14 compared to R-CHOP-21 in untreated stage III and IV B-cell NHL patients with Iranian ethnicity. Inclusion criteria: Age; sex; type of NHL; subtype; Ki-67 index; organomegaly; lymphadenopathy; radiotherapy; anatomic sites of NHL; recurrence. Exclusion criteria: cardiovascular; renal; hepatic disease (hepatitis B or hepatitis C; T-cell lymphoma;patients with initial neutrophil count <1.5×109 per L; initial platelet count <100×109 per L. Population, volume and time: patients with previously untreated stage III and IV indolent and aggressive B-cell NHL were randomly assigned by using a minimization method to receive six to eight cycles of either R-CHOP-21(administered every 21 days) or R-CHOP-14 (administered every 14 days with granulocyte colony-stimulating factor).143 patients were randomly enrolled in our study (66 patients in R-CHOP-14 group and 77 patients in R-CHOP-21), between 2011 and 2014. Side effect: Neutropenia,thrombocytopenia,anemia and etc

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010125791N1**
Registration date: **2016-01-17, 1394/10/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-01-17, 1394/10/27

Registrant information

Name

Masoud Sadeghi

Name of organization / entity

Kermanshah University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2013-01-01, 1391/10/12

Expected recruitment end date

2015-10-01, 1394/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of R-CHOP-21 vs. R-CHOP-14 for untreated stage III and IV B-cell Non-Hodgkin's Lymphoma

Public title

A treatment for Non-Hodgkin's Lymphoma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age; sex; type of NHL; subtype; Ki-67 index; organomegaly; lymphadenopathy; radiotherapy; anatomic sites of NHL; recurrence Exclusion criteria: cardiovascular; renal; hepatic disease (hepatitis B or hepatitis C; T-cell lymphoma;patients with initial neutrophil count <1.5×109 per L; initial platelet count <100×109 per L

Age

From **16 years** old to **82 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **143**

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
Ethics committe of Kermanshah University of Medical Sciences and Health Services

Street address
Kermanshah University Of Medical Sciences, Beheshti blv, kermanshah, iran Kermanshah Kermanshah Iran, Islamic Republic Of

City
Kermanshah

Postal code

Approval date
2016-01-05, 1394/10/15

Ethics committee reference number
KUMS.REC.1394.227

Health conditions studied

1

Description of health condition studied
Non-Hodgkin lymphoma, unspecified

ICD-10 code
C85.9

ICD-10 code description
Non-Hodgkin lymphoma, unspecified

Primary outcomes

1

Description
Survival

Timepoint
2 and 5 years

Method of measurement
Observtion

Secondary outcomes

1

Description
Neutropenia

Timepoint
every 14 days and every 21 days

Method of measurement
Experimental

Intervention groups

1

Description
R-CHOP-21:intravenous cyclophosphamide 750 mg/m2, doxorubicin 50 mg/m2, vincristine 1.4 mg/m2 (maximum dose 2 mg), and rituximab (MabThera®) 375 mg/m2 on day 1, and oral prednisolone 100 mg/m2 on days 1–5, administered every 21 days.

Category
Treatment - Drugs

2

Description
R-CHOP-14 group: intravenous cyclophosphamide 750 mg/m2, doxorubicin 50 mg/m2, vincristine 2 mg, rituximab(MabThera®) 375 mg/m2 on day 1, and oral prednisolone 100 mg on days 1–5, administered every 14 days with G-CSF.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Cancer Research Center

Full name of responsible person
Dr. Mehrdad Payandeh

Street address

City
Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Kermanshah University

Of Medical Sciences and Health Services

Full name of responsible person

Dr. Behrooz Hamzeh

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Kermanshah University Of Medical Sciences, Beheshti blv, kermanshah, iran Kermanshah Kermanshah Iran, Islamic Republic Of

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Kermanshah University Of Medical Sciences and Health Services

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

Kermanshah University of Medical Sciences

Full name of responsible person

Masoud Sadeghi

Position

MSc

Other areas of specialty/work

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Position

Assistant professor

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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