Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study for efficacy and safety between Zitux (Rituximab manufactured by AryoGen) and Mabthera on patients with chronic lymphocytic leukemia (CLL)

Protocol summary

Summary

The objective of this randomized, double blind trial is to compare the efficacy and safety of Mabthera® and Zitux (Rituximab manufactured by AryoGen) on patients with chronic lymphocytic leukemia (CLL) .In this study, 60 patients with CLL who meet the inclusion/exclusion criteria will be recruited and randomly assigned equally into two intervention or a control group. The patients in the intervention group will receive Zitux and in the control group will receive Mabthera® as same dosage and form.response to treatment according to national cancer institute response to treatment criteria for CLL will be measured after the intervention and compared between the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305296302N5**
Registration date: **2013-06-07, 1392/03/17**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-06-07, 1392/03/17

Registrant information

Name

Kamran Kamyar

Name of organization / entity

AryoGen Biopharma Company

Country

Iran (Islamic Republic of)

Phone

00982616102587،00982616101568

Email address

kamyark@aryogen.com

Recruitment status

Recruitment complete

Funding source

AryoGen Biopharma Company

Expected recruitment start date

2013-08-09, 1392/05/18

Expected recruitment end date

2013-12-09, 1392/09/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study for efficacy and safety between Zitux (Rituximab manufactured by AryoGen) and Mabthera on patients with chronic lymphocytic leukemia (CLL)

Public title

A comparative study between Zitux (Rituximab manufactured by AryoGen) and Mabthera on patients with chronic lymphocytic leukemia (CLL)

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: patient with chronic lymphocytic leukemia according to national cancer institute diagnostic criteria for CLL who hasn't been treated already or is new case of CLL or relapsed/refractory CLL with indication for treatment; Age between 18 to 75; Binet stage disease B,C; ECOG performance status: 0 to 1; CD20 positive; patient has indication for treatment in the beginning of study; written informed consent form.

exclusion criteria: Bil>2 mg/dl; Cr> 2 mg/dl; Alk-p> 2 times of upper limit normal; Trans aminase > 2 times of upper limit normal; Coexistence of serious active infection or underlying disorder(Hepatitis B,C, HIV positive, cardiopulmonary disease, recent MI, uncontrolled diabetes or HTN, seizure); HBSAg or HBCAb positive; other cancer treatments in the last 5 years; severe autoimmune hemolytic anemia, pregnancy or breast feeding exclusion criteria: Bil>2 mg/dl; Cr> 2 mg/dl; Alk-p> 2 times of upper limit normal; Trans aminase > 2 times of upper limit normal; Coexistence of serious active infection or underlying disorder(Hepatitis B,C, HIV positive, cardiopulmonary disease, recent MI, uncontrolled diabetes or HTN, seizure); HBSAg or HBCAb positive; other cancer treatments in the last 5 years; severe autoimmune hemolytic anemia, pregnancy or breast feeding

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **78**

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 committee of Iranian Blood Transfusion Organization

Street address
IBTO bldg, Hemmat Exp.Way, Next to the Milad Tower, Tehran, Iran

City
tehran

Postal code
14665-1157

Approval date
2013-03-16, 1391/12/26

Ethics committee reference number
378/پ

Health conditions studied

1

Description of health condition studied
chronic lymphocytic lukemia

ICD-10 code
C91.1

ICD-10 code description
Chronic lymphocytic leukaemia of B-cell type

Primary outcomes

1

Description
Overall response rate according to national cancer institute response to treatment criteria

Timepoint
2 and 4 months after beginning of treatment

Method of measurement
physical exam and laboratoty results according to national cancer institute response to treatment criteria

Secondary outcomes

1

Description
Complete response rate

Timepoint
2 and 4 months after beginning of treatment

Method of measurement
physical exam and laboratoty results according to national cancer institute response to treatment criteria

2

Description
Partial response rate

Timepoint
2 and 4 months after beginning of treatment

Method of measurement
physical exam and laboratoty results according to national cancer institute response to treatment criteria

3

Description
Stable disease rate

Timepoint
2 and 4 months after beginning of treatment

Method of measurement
physical exam and laboratoty results according to national cancer institute response to treatment criteria

4

Description
Progressive disease rate

Timepoint
2 and 4 months after beginning of treatment

Method of measurement
physical exam and laboratoty results according to national cancer institute response to treatment criteria

5

Description
CD20 reduction rate
Timepoint
monthly after beginning of treatment
Method of measurement
flucytometery

6

Description
Complete response rate according to flucytometery
Timepoint
monthly after beginning of treatment
Method of measurement
flucytometery

7

Description
side effect rate, fever
Timepoint
monthly during 4 months of treatment
Method of measurement
physical exam

8

Description
side effect rate, cardiovascular
Timepoint
monthly during 4 months of treatment
Method of measurement
physical exam

9

Description
side effect rate, digestive
Timepoint
monthly during 4 months of treatment
Method of measurement
physical exam

10

Description
side effect rate, hematologic
Timepoint
monthly during 4 months of treatment
Method of measurement
laboratoty results

11

Description
side effect rate, metabolic
Timepoint
monthly during 4 months of treatment
Method of measurement
physical exam and laboratoty results

12

Description
side effect rate, Musculoskeletal
Timepoint
monthly during 4 months of treatment
Method of measurement
physical exam

13

Description
side effect rate, respiratory
Timepoint
monthly during 4 months of treatment
Method of measurement
physical exam

14

Description
side effect rate, skin
Timepoint
monthly during 4 months of treatment
Method of measurement
physical exam

Intervention groups

1

Description
intervention group: combination therapy with (Fludarabine, Cyclophosphamide, Zitux) for 4 cycle with 28 days intervals as below: first treatment cycle: Zitux: 375 mg/m2 IV in first day Fludarabine: 25 mg/m2 IV in second to forth day Cyclophosphamide: 250 mg/m2 IV in second to forth day second to forth treatment cycles: Zitux: 500 mg/m2 IV in first day Fludarabine: 25 mg/m2 IV in first to third day Cyclophosphamide: 250 mg/m2 IV in first to third day
Category
Treatment - Drugs

2

Description
control group: combination therapy with (Fludarabine, Cyclophosphamide, Reditux) for 4 cycle with 28 days intervals as below: first treatment cycle: Reditux: 375 mg/m2 IV in first day Fludarabine: 25 mg/m2 IV in second to forth day Cyclophosphamide: 250 mg/m2 IV in second to forth day second to forth treatment cycles: Zitux: 500 mg/m2 IV in first day Fludarabine: 25 mg/m2 IV in first to third day Cyclophosphamide: 250 mg/m2 IV in first to third day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Iranian Blood Transfusion Organization

Full name of responsible person
Dr. Gholamreza Toogeh

Street address
IBTO bldg, Hemmat Exp.Way, Next to the Milad Tower, Tehran, Iran

City
tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
AryoGen Biopharma company

Full name of responsible person
Dr. Behrouz Vaziri

Street address
Cross Tajbakhsh Street, 24th Kilometer Makhsous, Tehran - Iran . AryoGen Biopharma Co.

City
Garmdareh

Grant name

Grant code / Reference number

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

Title of funding source
AryoGen Biopharma 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
AryoGen Biopharma company

Full name of responsible person
Dr. Kamran Kamyar

Position
General Practitioner/ Medical Manager

Other areas of specialty/work

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Cross Tajbakhsh Street, 24th Kilometer Makhsous, Tehran - Iran . AryoGen Biopharma Co.

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kamyark@aryogen.com

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Iranian Blood Transfusion Organization

Full name of responsible person
Dr. Mohammad Faranoush

Position
Pediatric Hematologist Oncologist Associate Professor

Other areas of specialty/work

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IBTO bldg, Hemmat Exp.Way, Next to the Milad Tower, Tehran, Iran

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Email
faranoush47@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person
Dr. Kamran Kamyar

Position

Other areas of specialty/work

Street address

City

Postal code

Phone
00

Fax

Email

Web page address

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