

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Safety and efficacy of Anti-Thymocyte Globulin (Zist Kowsar Pharmaceutical Company) in comparison with Anti-Thymocyte Globulin (Genzyme) for immunosuppressive induction therapy in adults with renal transplantation: A phase III, randomized, parallel, single blind , non-inferiority design

Protocol summary

Study aim

Determining safety and efficacy of Anti-Thymocyte Globulin (Kowsar biotech Company) in comparison with Anti-Thymocyte Globulin (Genzyme) for immunosuppressive induction therapy in adults with renal transplantation

Design

Randomized controlled trial, parallel, single blind with sample size of 129

Settings and conduct

129 renal transplant candidates who are blinded to intervention groups are randomly assigned to one group and receive one brand of thymoglobulin in addition to other equal routine drug regimen

Participants/Inclusion and exclusion criteria

Inclusion criteria: recipient age ≥ 18 years(donor age ≥ 5), willingness to sign the informed consent, renal graft from cadaver, Second graft (patients who had rejected the renal graft once can be enrolled 6-12 months after the rejection), Delayed onset of graft function OR reception from cadaver graft OR indication for receiving the investigated drug Exclusion criteria: Positive history of polyclonal Anti-T-Cell therapy, Known allergy to rabbit proteins, positive history of malignancy in 2 years Pregnancy or Lactation, willingness to pregnancy and not using a safe contraceptive method, positive serology for HTLV, HIV or HBV

Intervention groups

Two intervention groups: one group receives thymoglobulin (KBC) and the other group receives thymoglobulin (Genzyme)

Main outcome variables

Any adverse drug outcome and reaction, graft rejection, patient survival, graft survival, incidence of infection,

serious adverse events

General information

Reason for update

Adding actual sample size reached, actual recruitment start and end date, and trial completion date

Acronym

IRCT registration information

IRCT registration number: **IRCT20100127003200N6**

Registration date: **2019-01-15, 1397/10/25**

Registration timing: **prospective**

Last update: **2025-02-21, 1403/12/03**

Update count: **3**

Registration date

2019-01-15, 1397/10/25

Registrant information

Name

Kazem Heidari

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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k_heidari@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

2019-04-26, 1398/02/06

Actual recruitment end date

2022-05-10, 1401/02/20

Trial completion date

2022-11-19, 1401/08/28

Scientific title

Safety and efficacy of Anti-Thymocyte Globulin (Zist Kowsar Pharmaceutical Company) in comparison with Anti-Thymocyte Globulin (Genzyme) for immunosuppressive induction therapy in adults with renal transplantation: A phase III, randomized, parallel, single blind , non-inferiority design

Public title

Safety and efficacy of Anti-Thymocyte Globulin (Zist Kowsar Pharmaceutical Company) in comparison with Anti-Thymocyte Globulin (Genzyme) for immunosuppressive induction therapy in adults with renal transplantation

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age >18 years (donor age >= 5) for recipient ability and willingness to sign the informed consent Reception of kidney from cadaver OR second graft (already rejected a kidney more than 6-12 month ago) OR indication for receiving the investigated drug

Exclusion criteria:

Positive history of polyclonal Anti-T-Cell therapy Known allergy to Rabbit proteins Positive history of malignancy in 2 years(excluding stem cell , squamous cell, bladder malignancies and asymptomatic invasive papillary renal cell cancer with less than 5 cm size) Pregnancy Lactating mother Willingness to pregnancy and not using a safe contraceptive method Positive serology for: HTLV, HIV or HBV

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **129**

Actual sample size reached: **119**

Randomization (investigator's opinion)

Randomized

Randomization description

random sequence for patients are made online using "sealed envelope" website. Randomized blocks are constructed for 129 patients. Codes are labelled on investigational drugs. after including each patient, site nurse calls the medical unit of company and receives the proper randomization code assigned to a special drug.

Blinding (investigator's opinion)

Single blinded

Blinding description

Drug packages are similar and labelled for investigational use. Patients are blinded to assigned therapy (active or standard drug) and group.

Placebo

Not used

Assignment

Parallel

Other design features

Relation of sample size for reference drug to test drug is 1:1.33

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Qods street

City

Tehran

Province

Tehran

Postal code

1111111111

Approval date

2019-01-06, 1397/10/16

Ethics committee reference number

IR.TUMS.VCR.REC.1397.722

Health conditions studied**1****Description of health condition studied**

Renal transplantation

ICD-10 code

Z94.0

ICD-10 code description

Kidney transplant status

Primary outcomes**1****Description**

Any adverse reaction

Timepoint

Any time after intervention

Method of measurement

Clinical or laboratory data

2

Description

Graft rejection

Timepoint

After 6 months

Method of measurement

Investigator documentation during follow-up

3

Description

Patient death/survival

Timepoint

After graft to end of follow up

Method of measurement

Investigator documentation during follow-up

4

Description

Graft loss

Timepoint

After graft to end of follow up

Method of measurement

Investigator documentation during follow-up

5

Description

incidence of infection (especially CMV)

Timepoint

After graft to end of follow up

Method of measurement

Periodic Lab data during follow up

6

Description

Serious adverse events

Timepoint

After graft to end of follow up

Method of measurement

Investigator documentation during follow-up

Secondary outcomes

1

Description

Delayed graft function (DGF)

Timepoint

During the first 7 days after transplantation

Method of measurement

Having dialysis during the first 7 days after transplantation

2

Description

Hospitalization time after transplantation

Timepoint

Graft to discharge time

Method of measurement

Hospital records

3

Description

T-cell lymphocyte count

Timepoint

Before and after drug injection

Method of measurement

Lab data: Complete blood count

Intervention groups

1

Description

Intervention group 1: 1- TGlobulin (Kowsar biotech Co.): 1-1.5 mg/kg/d for 4 days (Total dose of 3-7 mg/kg for each patient) 2- Cellcept 1gr/stat then 1gr/BD or Myfortic 720 mg/stat then 720 mg/BD 3- Tacrolimus capsule 1mg/kg/stat then 0.07 mg/kg/d 4- Steroid 1gr/stat then 1mg/kg/d

Category

Treatment - Drugs

2

Description

Intervention group 2: 1- Thymoglobulin (Genzyme): 1-1.5 mg/kg/d for 4 days (Total dose of 3-7 mg/kg for each patient) 2- cellcept 1gr/stat then 1gr/BD or Myfortic 720 mg/stat then 720 mg/BD 3- Tacrolimus capsule 1mg/kg/stat then 0.07 mg/kg/d 4- Steroid 1gr/stat then 1mg/kg/d

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Monir-Sadat Hakemi

Street address

North Kargar street

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Tehran

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1411713135

Phone

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Email

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2

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Mohammad Reza Khatami

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Kowsar Biotechnology company

Full name of responsible person

Siroos Zeinali

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Email

zeinali@gmail.com

Web page address

<http://kawsarbiotech.com/>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kowsar Biotechnology company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Industry

Person responsible for general inquiries

Contact**Name of organization / entity**

Pasture Institute of Iran

Full name of responsible person

Mehdi Behdani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biotechnology

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

Ph.D.

Other areas of specialty/work

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Because of confidentiality and regulatory limitation

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available