Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 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)

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+98 21 6649 5948

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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
City
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Province
Tehran
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1411713135
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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
Street address
N0 41, Majlesi st., Valiasr Street
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Phone
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Fax
+98 21 8893 9139
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
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Person responsible for updating data

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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