Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

A post-marketing surveillance for the Evaluation of the safety of TGlobulin25 (manufactured by KBC) for the induction of immunosuppressive therapy in adult kidney transplant candidates

Protocol summary

Study aim
Investigating the safety of T-globulin 25
Design
Post market, single arm, phase IV clinical trial on 100 patients
Settings and conduct
Patients referred to Abu Ali Sinai hospital in Shiraz will be first visited by the attending physician and then after assessing the eligibility criteria, they enter the study and the patient's file will be used to collect the required information regarding the safety of T-globulin 25. The duration of the study will be 52 weeks for each patient.
Participants/Inclusion and exclusion criteria
Kidney transplant candidate patients referred to Abuali Sina hospital in shiraz, receiving Tglobulin 25 as part of the induction of immunosuppressive therapy, The age of the transplant recipient should be more than 18 years and less than 65 years, and the donor should be more than 5 years and less than 60 years, able to understand the study and sign the written informed consent. History of previous treatment with anti-T cell polyclonal agents, Panel-Reactive Antibody (PRA)> 20%, Known allergy to rabbit proteins, Evidence of malignancy in the past 2 years, pregnant or lactating females, Patients with serological evidence of HIV, HTLV, HCV, HBV, WBC< 2000 and/or Plt< 50000 when receiving Tglobulin 25, patients receiving organs other than kidney, candidates of second kidney transplant, donor Serum creatinine> 4, ischemic time> 4 hours.
Intervention groups
Patients receiving a total dose of 5-6 mg/kg Tglobulin 25 for 4 days according to the actual body weight
Main outcome variables
Delayed graft function

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20201230049888N1**
Registration date: **2022-11-09, 1401/08/18**
Registration timing: **prospective**

Last update: **2022-11-09, 1401/08/18**
Update count: **0**
Registration date
2022-11-09, 1401/08/18

Registrant information
Name
Behnaz Hedayatjoo
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-11-22, 1401/09/01
Expected recruitment end date
2023-11-22, 1402/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

A post-marketing surveillance for the Evaluation of the safety of TGlobulin25 (manufactured by KBC) for the induction of immunosuppressive therapy in adult kidney transplant candidates

Public title

A post-marketing surveillance for the Evaluation of the safety of TGlobulin25 for the induction of immunosuppressive therapy in adult kidney transplant candidates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Kidney transplant candidate patients referred to Abuali sina hospital in shiraz, receiving Tglobulin 25 for induction of immunosuppressive therapy. The age of the transplant recipient should be more than 18 years and less than 65 years, and the donor should be more than 5 years and less than 60 years. Able to understand the study and sign the written informed consent

Exclusion criteria:

History of previous treatment with anti-T cell polyclonal agents Panel-Reactive Antibody (PRA)> 20% Known allergy to rabbit proteins Evidence of malignancy in the past 2 years pregnant or lactating females Patients with serological evidence of HIV, HTLV, HCV, HBV WBC< 2000 and/or Plt< 50000 when receiving Tglobulin 25 patients receiving organs other than kidney candidates of second kidney transplant donor Serum creatinine> 4 ischemic time> 4 hours

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی شیراز

Street address

Secretariat of the Research Ethics Committee of the University, Research and Technology Vice-Chancellor, 7th Floor, Central Building, Shiraz University of Medical Sciences, Zand St, Shiraz

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Province

Fars

Postal code

7134814336

Approval date

2022-06-22, 1401/04/01

Ethics committee reference number

IR.SUMS.REC.1401.208

Health conditions studied

1

Description of health condition studied

kidney transplantation

ICD-10 code

Z94.0

ICD-10 code description

Kidney transplant status

Primary outcomes

1

Description

Delayed graft function

Timepoint

All along the study duration until one year after transplantation surgery

Method of measurement

kidney transplant rejection approved by biopsy or clinical symptoms and laboratory tests

Secondary outcomes

1

Description

Mortality

Timepoint

End of 52 weeks

Method of measurement

living status of the patient

2

Description

adverse effects

Timepoint

throughout the 52 weeks

Method of measurement
patients self report, clinical symptoms, and laboratory data

3

Description
Acute rejection
Timepoint
daily up to 14 days
Method of measurement
clinical symptoms such as creatinine rise, and final diagnosis based on histopathology

4

Description
chronic rejection
Timepoint
monthly up to 12 months
Method of measurement
clinical symptoms such as creatinine rise, and final diagnosis based on histopathology

Intervention groups

1

Description
Intervention group: Patients receiving 5-6 mg/kg total dose of Tglobulin 25 for 4 days according to the actual body weight
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Abu-Ali Sina hospital
Full name of responsible person
Saman Nikeghbalian
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Sponsors / Funding sources

1

Sponsor
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Kawsar biotech company
Full name of responsible person
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NO.41, Third floor, Irna st, Fatemi Square, Tehran , Iran
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Postal code
1595645513
Phone
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Email
Kawsar_biotech@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kawsar biotech 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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
ArtaZist Pharmed Co
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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
No - There is not a plan to make this available