

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 26 3273 5848

Email address

b.hedayatjoo@artapharmed.com

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

City

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Province

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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

Street address

Sadra, Shiraz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kawsar biotech company

Full name of responsible person

Sirous Zeinali

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NO.41, Third floor, Irna st, Fatemi Square, Tehran , Iran

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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

Full name of responsible person

Behnaz Hedayatjoo

Position

Clinical Trial Supervisor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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Position

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Specialist

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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