

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of clinical outcome of induction immunosuppressive therapy with thymoglobuline and standard therapy in kidney transplantation

Protocol summary

Summary

The study was designed as a prospective, randomized trial to assess the safety and efficacy of thymoglobulin in renal transplantation. This study will be included 106 patients who will be transplanted in Golestan hospital. The patients who have full-matched Human Leukocyte Antigens with donor, have contraindication for thymoglobulin or have active transplanted organ other than the kidney, will be excluded from the study. The patients will be randomly divided into two groups. 53 patients will be assigned to the control group and 53 patients will be assigned into thymoglobulin group. Standard immunosuppressive therapy is identical in both groups and consisted of corticosteroid, mycophenolate mofetil and cyclosporine or tacrolimus. Second group will receive thymoglobulin, in addition to the standard immunosuppressive therapy. The patients will be followed for one year and the rate of transplanted kidney rejection, function of transplanted kidney and side effect of medications will be evaluated in both groups and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050933884N1**

Registration date: **2017-06-03, 1396/03/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-03, 1396/03/13

Registrant information

Name

Leila Sabetnia

Name of organization / entity

Jundishapour University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3441 2263

Email address

sabetnia-l@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahwaz University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of clinical outcome of induction immunosuppressive therapy with thymoglobuline and standard therapy in kidney transplantation

Public title

Comparison the rate of acute transplant rejection and side effect of therapy with and without thymoglobuline in kidney transplantation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : all the patients who are transplanted in Golestan hospital
Exclusion criteria : donor and recipient full-matched HLA; contraindication for administration of thymoglobulin; presence of organ transplantation other than the kidney

Age
No age limit
Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **106**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ahwaz University of Medical Sciences

Street address
Farvadin st, Golestan distcrit

City
Ahwaz

Postal code

Approval date
2015-08-08, 1394/05/17

Ethics committee reference number
IR.AJUMS.REC.1394.329

Health conditions studied

1

Description of health condition studied
Kidney Transplantation status

ICD-10 code
Z94.0

ICD-10 code description
kidney transplant status

Primary outcomes

1

Description
Glomerular Filtration Rate

Timepoint

Monthly
Method of measurement
cc per minute,MDRD equation

Secondary outcomes

1

Description
Side Effects of Medications

Timepoint
Monthly

Method of measurement
Questionnaire and Lab data

Intervention groups

1

Description
standard therapy and Induction therapy with Thymoglobulin

Category
Treatment - Drugs

2

Description
Standard therapy without thymoglobulin

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ahwaz Golestan Hospital

Full name of responsible person
Sabetnia Leila

Street address
Golestan Hospital, Golestan Distcrit

City
Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahwaz Jundishapour University of Medical Sciences

Full name of responsible person
Shahbazian Heshmatollah MD

Street address
Farvadin st, Golestan distcrit

City
Ahwaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahwaz Jundishapour University of Medical Sciences

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

Golestan Hospital

Full name of responsible person

Sabetnia Leila

Position

Specialist/ Subspecialist assistant

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahwaz Jundishapour University of medical sciences

Full name of responsible person

Shahbazian Heshmatollah

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Professor/Subspecialist

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Full name of responsible person

Sabetnia Leila

Position

Specialist/Subspecialist assistant

Other areas of specialty/work

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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