

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Evaluation of the Clinical safety and efficacy of Suprimun compared with Cellcept in renal transplant recipients

Protocol summary

Summary

Objectives: Evaluation of the Clinical safety and efficacy of Suprimun compared with Cellcept in renal transplant recipients. Design: Balanced block parallel Randomization control trial study. Setting and Conduct: 60 eligible patients who recently have kidney transplant from Imam Reza hospital of Kermanshah have been included in the study gradually during 4 months and follow up for 6 months. Qualified Participants: 60 kidney transplanted patients Intervention: Use of Suprimun (Group A) and Cellcept (Group B) in those transplanted patients who received the triple scheme consisting of Corticosteroids, Cyclosporine and Suprimun/Cellcept from the beginning and follow up for 6 months after surgery. Main outcome measures (variables): GFR measurement; Episodes of Acute Renal rejection; Dialysis necessary; Presence of side effects, Patient situation (dead, alive).

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Recruitment status

Recruitment complete

Funding source

Kermanshah University Of Medical Sciences,

Expected recruitment start date

2014-04-25, 1393/02/05

Expected recruitment end date

2014-08-27, 1393/06/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014072118548N1**

Registration date: **2014-08-19, 1393/05/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-19, 1393/05/28

Registrant information

Name

Hamed Mohamadian Shoeili

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Scientific title

Evaluation of the Clinical safety and efficacy of Suprimun compared with Cellcept in renal transplant recipients

Public title

Evaluation of the Clinical Safety and Efficacy of Suprimun in Renal Transplant Recipients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Have signed the informed consent form; Are male or females between the age of 18 and 55 years old; Are going to be transplanted (kidney) for the first time; Are willing to begin and continue treatment with the triple scheme (corticosteroids, cyclosporine and Suprimun/Cellcept®); Are going to benefit from this triple scheme; Are in good general medical conditions; Agree to use birth control methods; Have ABO compatibility; Are taking MMF with a total dose of 2 gr/d (4 tablets); Are receiving transplant from non-relative and alive donors. Exclusion Criteria : Receive

Mycophenolate Mofetil from another brandname; Have active Hepatitis B or C; Is intolerant to any of the drugs of the triple scheme; Have any medical condition that can interfere with the normal follow up of the study; Has a history of MI, life-threatening arrhythmia or CVA in the last 6 month , history of malignancy, pregnancy and breastfeeding; Have participated in another clinical study 3 months ago or less before the selection visit; Any induction Therapy (ATG , IL2 receptor inhibitor) before or during the surgery; Any renal rejection with non-relative reason to Mycophenolate drug during 48h after the surgery.(Vascular rejection, urological rejection); Are being transplanted for 2nd or 3rd time, or from cadaver; Be addicted to alcohol or illegal drugs;Be HIV positive

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Kermanshah University of Medical Sciences

Street address

Shahid Beheshti.Blv,

City

Kermanshah

Postal code

Approval date

2013-12-17, 1392/09/26

Ethics committee reference number

50646

Health conditions studied

1

Description of health condition studied

Comparative Interventional Treatment for reducing the renal transplant rejection

ICD-10 code

T86.1

ICD-10 code description

kidney transplant rejection

Primary outcomes

1

Description

Glomerular Filtration Rate(GFR)

Timepoint

During 6 months after transplant(at week 2,6th month)

Method of measurement

Plasma Creatinine, Age & weight and gender of patient

Secondary outcomes

1

Description

Dialysis requirement due to nephrologist decision

Timepoint

During 6 months after transplant(at week 3,4,6,8,10,12,16,20,24)

Method of measurement

During 6 months after transplant(at week 3,4,6,8,10,12,16,20,24)

2

Description

Incidence of acute renal rejection

Timepoint

During 6 months after transplant(at week 3,4,6,8,10,12,16,20,24)

Method of measurement

Renal Biopsy

3

Description

Presence of Adverse events

Timepoint

During 6 months after transplant(at week 3,4,6,8,10,12,16,20,24)

Method of measurement

Leukopenia, thrombocytopenia, gastrointestinal discomfort, malignancy, viral infections

4

Description

Situation of the patients

Timepoint

During 6 months after transplant(at week 3,4,6,8,10,12,16,20,24)

Method of measurement

Alive or dead

Intervention groups

1

Description

Group A(Intervention): They get Suprimun tab which is contained 500 mg mycophenolate mofetil.The total dose is 2gr per day which was used 1gr twice a day before meal.

Category

Treatment - Drugs

2

Description

Group B(control): They get Cellcept capsule which is contained 500 mg Mychophenolate mofetil.The total dose is 2gr per day which was used 1gr twice a day before meal.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Hamed Mohamadian Shoeili

Street address

Imam Reza hospital

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Kermanshah University Of Medical Sciences

Full name of responsible person

Koroush Hamzehee

Street address

Shahid Beheshti Blv, Kermanshah

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Deputy of Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Hamed Mohamadian Shoeili

Position

Resident of internal medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Person responsible for updating data

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Position

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Web page address**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