

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 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: 100 qualified patients who recently have kidney transplant from 4 clinical sites have been included in the study gradually during 4 months and follow up for 6 months. Qualified Participants: 100 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 (at weeks 2, 6 months after surgery); Episodes of Acute Renal rejection; Dialysis necessary; Presence of side effects, Patient situation (dead, alive).

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Actover pharmaceutical company

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-06-22, 1392/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013012612274N1**

Registration date: **2014-03-25, 1393/01/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-03-25, 1393/01/05

Registrant information

Name

Sepideh Shakeri

Name of organization / entity

Actoverco

Country

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; Have a BMI (body mass index) between 18.5 and 24.9; Are male or females between the age of 18 and 60 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; Have low immunologic risk (PRA

< 20%, high HLA 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); Taking medications that interfere with the action of the drug, including: Magnesium and Aluminum Hydroxide, Cholestyramine, phenytoin , diltiazem and Probenecid, any live vaccines; 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 **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

1

Registry name

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

Secondary trial Id

AS4/910606/118

Registration date

2012-08-27, 1391/06/06

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics commetee of Shahid Beheshti Medical University,Urology Research Center

Street address

No.44,Beside Labafi Nejad Hosp,Boostan 9 Ave,Pasdaran Ave,Tehran,Iran

City

Tehran

Postal code

Approval date

2012-09-05, 1391/06/15

Ethics committee reference number

A.1615

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

Rises of Plasma Creatinine

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

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

4**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

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 Mycophenolate 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**

Hashemi Nejad Hospital

Full name of responsible person

Dr Tahereh Malakutian

Street address

Hasheminejad Kidney Center Valinejad St., Valiasr
Ave., Vanaq Sq. Valinejad alley.

City

Tehran

2**Recruitment center****Name of recruitment center**

Labafi Nejad Hospital

Full name of responsible person

Dr Mohsen Nafar

Street address

Ninth Boostan, Pasdaran st.

City

Tehran

3**Recruitment center****Name of recruitment center**

Modarres Hospital

Full name of responsible person

Dr Hassan Argani

Street address

Intersection of Yadegar-e Emam Highway and Sa'adat
Abad

City

Tehran

4**Recruitment center****Name of recruitment center**

Shariati Hospital

Full name of responsible person

Dr Iraj Najafi

Street address

North Kargar Ave - Jalal AL- Ahmad

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice-Chancellor for Research, Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Afshin Zarghi, PhD

Street address

Shahid Beheshti University of Medical Sciences,Next
to Taleghani Hospital,Shahid Arabi St.,Yemen
St.,Velenjak St. , Shahid Chamran Highway

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice-Chancellor for Research, Shahid Beheshti 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

Actover Pharmaceutical Company

Full name of responsible person

Farhad Hatami (MD)

Position

Monitor / MD

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Actover Pharmaceutical company

Full name of responsible person

Sepideh Shakeri (MD)

Position

Clinical Investigator / MD

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Nephrology/Urology Research Center of Shahid
Beheshti Medical University

Full name of responsible person

Hassan Argani (MD)

Position

Principle Investigator / Nephrologist

Other areas of specialty/work

Street address

No.44, Beside Labafi Nejad Hosp, Boostan 9 ave,
Pasdaran ave, Tehran , Iran

City

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Postal code

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