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).

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

Iran (Islamic Republic of)

Phone

+98 21 2206 8479

Email address

sepideh.shakeri@actoverco.com

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

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 60years 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 reduceing 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 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
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 scientific inquiries

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Name of organization / entity
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Principle Investigator / Nephrologist
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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