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Induction therapy in transplantation

Submission date 29/02/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 25/04/2016	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 18/04/2016	**Condition category** Signs and Symptoms	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
In a healthy person, the kidneys are responsible for filtering out the waste products and excess water in the blood, and converting them into urine. If the kidneys suddenly stop working (acute kidney injury) or are suffering from severe, long-term disease of the kidneys (chronic kidney failure) then the body is unable to get rid of the waste products building up in the blood. Eventually, the kidneys are no longer able to support the body's needs (end stage renal disease) and so a treatment to replace the work of the failed kidneys is needed. Kidney transplantation is the best treatment for end-stage renal disease. One of the biggest risks after a patient has had a kidney transplant is that the immune system (the body's natural defense) attacks the new kidney as it recognizes it as foreign tissue (acute transplant rejection). The main way of preventing this from happening is by treating patients with drugs that suppress the activity of the immune system to ensure the transplant survives (induction therapy). Thymoglobin is a medication commonly used to help prevent and treat rejection in kidney transplant patients. It can be very effective however the best possible dose to use is not yet known. The aim of this study is to compare three different doses of thymoglobin in order to find the most safe and effective dose.

Who can participate?
Adult kidney transplant recipients.

What does the study involve?
Participants are randomly allocated to one of three groups. Those in the first group receive a total of 4.5 mg/kg thymoglobulin over three days, which involves receiving 1.5 mg/kg each day through a drip for six hours. Those in the second group receive a total of 4.5 mg/kg thymoglobulin, which is all given through a drip over six hours on one day. Those in the third group receive a total of 6 mg/kg thymoglobulin over three days, which involves receiving 2 mg /kg each day through a drip for six hours. Participants in all groups are followed up six months and one year after their transplant in order to find out the amount who have suffered from transplant rejection and serious infections.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with taking part in this study.

Where is the study run from?
Labbafinejad Hospital (Iran)

When is the study starting and how long is it expected to run for?
November 2012 to April 2015

Who is funding the study?
Labbafinejad Hospital (Iran)

Who is the main contact?
Dr Behrang Alipour

Contact information

Type(s)
Scientific

Contact name
Dr Behrang Alipour

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The appropriate dose of thymoglobulin induction therapy in kidney transplantation

Study objectives
Giving thymoglobulin in a 4.5 mg /kg in 3 days protocol is safe with lower infectious complications in comparison with higher doses or bolus protocols.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Urology Nephrology Research Center, Shahid Beheshti Medical University (UNRC-SBMU), 01/01/2013

Study design
Single-centre open-label tree-arm randomized parallel trial

Primary study design
Interventional

Secondary study design

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Acute transplant rejection

Interventions
Participants are randomly allocated to one of three groups.

Group 1: Participants are treated with a total of 4.5 mg/kg in 3 days, receiving 1.5 mg/kg in each days infused over 6 hours
Group 2: Participants are treated with a total of 4.5 mg/kg single bolus dose), infused over 6 hours in one day
Group 3: Participants are treated with total dose 6 mg/kg in 3 days, receiving 2 mg/kg in each day infused over 6 hours

The first dose of thymoglobulin is given over six hours beginning intra-operatively (peri perfusion of the allograft). Subsequent doses are given over at least four hours and withheld if the platelet count drops below 50,000 per mm3 or the white blood cell (WBC) count drops below 2,000 per mm3. An initial WBC of >2000/ mm2 and PLT of > 75000/mm2 is required to start treatment. If the platelet count is between 50,000–75,000 per mm3 or the WBC count is between 2,000–3,000 per mm3 the thymoglobulin dose is halved.

Intervention Type
Drug

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
Thymoglobulin

Primary outcome measure

Rate and severity of acute rejection during the first year post-transplantation is measured using kidney biopsy at 6 months post-transplantation.

Secondary outcome measures
1. Time to and the rate of serious infections are measured using history of admissions and blood culture and urine culture taken at each time admission for one year after transplantation
2. CMV infection rate is measured using CMV Ag pp65 antigenemia confirmed by CMV PCR monthly for one year after transpmantation
3. Length of hospital stay is measured through patient note review for any hospital admission within one year of transplantation
4. Rate of readmission is measured through patient note review for one year after transplantation
5. Incidence of hematologic abnormalities and renal function are assessed by measuring serum creatinine and estimating glomerular filtration rate using CKD-EPI using CKD-EPI and checking CBC (diff) monthly at each visit for one year after transplantation

Overall study start date
20/11/2012

Completion date
15/04/2015

Eligibility

Key inclusion criteria
1. Aged between 18 and 65 years
2. Positive Panel Reactive Antibody (PRA) (> 0%) at the time of transplantation
3. History of previous transplantation
4. Extended criteria donor (ECD)
5. Cold ischemia time > 6 hours

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90

Key exclusion criteria
1. Multiple organ transplants
2. Serological evidence of human immunodeficiency virus or active hepatitis B and C in recipients or donors

Date of first enrolment
10/01/2013

Date of final enrolment
21/02/2013

Locations

Countries of recruitment
Iran

Study participating centre
Labbafinejad Hospital
9th Boostan Street
Pasdaran Avenue
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Iran
1256365485

Sponsor information

Organisation
Shahid Beheshti Medical University

Sponsor details
Chronic Kidney Disease Research Center (CKDRC)
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2152565458

Sponsor type
University/education

ROR
https://ror.org/034m2b326

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Labbafinejad Hospital

Results and Publications

Publication and dissemination plan
Planned publication in an ISI journal.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available