

# Induction therapy in transplantation

<b>Submission date</b> 29/02/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/04/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/04/2016	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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). Thymoglobulin 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 thymoglobulin 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

**Contact details**  
Shahid Beheshti Medical University  
Chronic Kidney Disease Research Center (CKDRC)  
9th Boostan Street  
Pasdaran Avenue  
Tehran  
Iran  
1256958585

## 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)**

**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 mm<sup>3</sup> or the white blood cell (WBC) count drops below 2,000 per mm<sup>3</sup>. An initial WBC of >2000/ mm<sup>2</sup> and PLT of > 75000/mm<sup>2</sup> is required to start treatment. If the platelet count is between 50,000–75,000 per mm<sup>3</sup> or the WBC count is between 2,000–3,000 per mm<sup>3</sup> 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 transplantation
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

Tehran

Iran

1256365485

## **Sponsor information**

**Organisation**

Shahid Beheshti Medical University

**Sponsor details**

Chronic Kidney Disease Research Center (CKDRC)

9th Boostan Street

Pasdaran Avenue

Tehran

Iran

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