

# Can losartan reduce fibrosis and slow the decline of kidney function in kidney transplant patients?

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<b>Registration date</b> 25/06/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 23/06/2016	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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 which replaces the work of the failed kidney is needed. Kidney transplantation is the best treatment for end-stage renal disease, however there is a risk that the new kidney (graft) will fail. Chronic allograft nephropathy is the biggest cause of graft failure in kidney transplant patients. Losartan is a type of medication called an angiotensin II receptor blocker (ARB), which is mainly used to treat high blood pressure. Lab-based studies have shown that it can decrease the production of chemicals in the body called TGF  $\beta$  and miR 21, which are major causes of chronic allograft nephropathy, by blocking the genes that code for them. The aim of this study is to find out whether losartan can reduce fibrosis and improve graft function in kidney transplant patients.

### Who can participate?

Adults who have had their first kidney transplant from an unrelated, living donor.

### What does the study involve?

Participants are randomly allocated to one of two groups. Participants in the first group receive take tablets containing 25mg losartan every day for six months after their transplant. Participants in the second group receive no losartan, but can be treated with medication to lower blood pressure (except ACE inhibitors or other angiotensin II receptor blockers). After six months, participants have a sample of blood taken to measure how effectively the new kidney is working.

### What are the possible benefits and risks of participating?

Participants who take the losartan may benefit from a lower chance of loss of function of their new kidney. There is a small risk of developing hyperkalemia (high potassium) when taking

losartan, however patients will be closely monitored to avoid this. There is a risk of bleeding, discomfort or bruising during and after blood samples are taken.

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

When is the study starting and how long is it expected to run for?  
September 2013 to November 2015

Who is funding the study?  
Shahid Beheshti Medical University (Iran)

Who is the main contact?  
Dr Behrang Alipour

## Contact information

**Type(s)**  
Public

**Contact name**  
Dr Behrang Alipour

**Contact details**  
Chronic Kidney Disease Research Center (CKDRC)  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**  
The effect of the renin-angiotensin system inhibitors after renal transplantation on chronic allograft nephropathy through down regulation of TGF  $\beta$  and miR 21 in kidney transplant patients Labbafinejad center of Tehran

**Study objectives**

Losartan is effective at reducing fibrosis and TGF- $\beta$ , and slowing the decline of kidney function in kidney transplant patients.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Urology Nephrology Research Center, Shahid Behehsti Medical University (UNRC-SMBU)

**Study design**

Single-centre randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

No specific participant information sheet available, please use the contact details below to request a further information.

**Health condition(s) or problem(s) studied**

Allograft nephritis

**Interventions**

Participants are randomly allocated to one of two groups.

Intervention group: Participants receive 25mg oral losartan daily for six months post transplantation.

Control group: Participants receive nothing or other antihypertensive drug except ACEi, ARB.

Participants in both groups are followed up at 6 months.

**Intervention Type**

Drug

**Phase**

Phase I/II

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

Losartan

**Primary outcome measure**

1. Graft function is determined by measuring eGFR at 48 hours, 3 and 6 months post transplantation
2. Fibrosis is measured by measuring TGF- $\beta$  and miR 21 levels using real time PCR at 48 hours, 3 and 6 months post transplantation

**Secondary outcome measures**

No secondary outcome measures.

**Overall study start date**

10/09/2013

**Completion date**

19/11/2015

## Eligibility

**Key inclusion criteria**

1. First kidney transplantation of living unrelated donor
2. Compliance to losartan
3. No allergic reaction to losartan
4. Agreement to participate in the study

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

50

**Key exclusion criteria**

1. Second transplant
2. Cadaveric transplant
3. Acute rejection during first week after transplantation
4. Delayed graft function during first week after transplantation

**Date of first enrolment**

19/11/2013

**Date of final enrolment**

21/12/2013

## Locations

**Countries of recruitment**

Iran

**Study participating centre**

**Labbafinejad Hospital**

Boostan 9th Street

Pasdaran Avenue

Tehran

Iran

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## **Sponsor information**

**Organisation**

Shahid Beheshti Medical University

**Sponsor details**

Chronic Kidney Disease Research Center (CKDRC)

9th Boostan Street

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Tehran

Iran

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**Sponsor type**

University/education

**ROR**

<https://ror.org/034m2b326>

## **Funder(s)**

**Funder type**

University/education

**Funder Name**

Shahid Beheshti Medical University

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in the Iranian Journal of Kidney Diseases.

**Intention to publish date**

19/11/2016

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not expected to be made available