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

Submission date
29/02/2016

Recruitment status
No longer recruiting

Registration date
25/06/2016

Overall study status
Completed

Last Edited
23/06/2016

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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 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 β 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

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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 β and miR 21 in kidney transplant patients Labbafinejad center of Tehran

Study objectives
Losartan is effective at reducing fibrosis and TGF-β, 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-β 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
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1213226544

Sponsor information

Organisation
Shahid Beheshti Medical University

Sponsor details
Chronic Kidney Disease Research Center (CKDRC)
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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