

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Assessment of Anti-inflammatory effect of Azithromycin on kidney donor and potential effect on recipient

Protocol summary

Summary

The aim of this study is to determine the anti-inflammatory effects of azithromycin in the grafted kidney function. Inclusion criteria are: all selected patients for nephrectomy (live or cadaver). Exclusion criteria included drug abuse; history of susceptibility to azithromycin; severe cardiovascular disorders. In this double blind study patients randomly will be divided into two groups (Random permutation block sampling). 1- Azithromycin group: one gram azithromycin will be administered 24 hours before the operation to live or cadaver kidney donor. 2- Placebo group: The patients of this group will be given 1 gram of placebo, 24 hours before the operation. Patients will follow-up 12 weeks. Possible side effects in patients will be recorded. The examination will be carried out at intervals of days before the operation, 24, 48 and 96 hours after surgery in donors and recipients and also 30 days and 90 days after transplantation in recipients. Initial outcome will be kidney function (measured by GFR), secondary outcome will be donor's pain and third outcome will be laboratory inflammatory markers in the donor and recipients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201606141853N11**

Registration date: **2016-09-05, 1395/06/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-05, 1395/06/15

Registrant information

Name

Siavash Falahatkar

Name of organization / entity

Urology Research Center

Country

Iran (Islamic Republic of)

Phone

+98 13 3352 5259

Email address

urc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Urology Research Center, Guilan University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of Anti-inflammatory effect of Azithromycin on kidney donor and potential effect on recipient

Public title

Assessment of Anti-inflammatory effect of Azithromycin on kidney donor and potential effect on recipient

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: Alive or cadaveric donor; Sign the inform consent by donor or Family of cadaver Exclusion criteria: Allergic components or allergic to various brands of Azithromycin; Severe medical disease like heart, liver, renal, hematological; respiratory, cardiovascular,

psychiatric or other problem pre transplantation in donor; Consumption of other medication including Macrolides family; Involvement in additional clinical trials at the same time

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 36

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Patients in this study will be randomized by Random Permutation Block.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Opposite Sepah Bank, Western Shahid Beheshti Blvd., Gaz Square

City

Rasht

Postal code

41938-93345

Approval date

2016-06-21, 1395/04/01

Ethics committee reference number

IR.GUMS.REC.1395.105

Health conditions studied

1

Description of health condition studied

Transplanted kidney function

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

GFR

Timepoint

1 day, 2 days, 4 days, 30 days and 90 days after transplantation

Method of measurement

Cockcroft-Gault Equation

Secondary outcomes

1

Description

Complication

Timepoint

1 day, 2 days, 4 days, 30 days and 90 days after transplantation

Method of measurement

Registration of physical examination, medical history and paraclinical findings

2

Description

Pain score in donors

Timepoint

1 day, 2 days and 4 days after transplantation

Method of measurement

Visual Analog Scale (VAS)

Intervention groups

1

Description

Intervention group: Capsule of Azithromycin 1 g, 24 hours before nephrectomy, Made in Iran

Category

Treatment - Drugs

2

Description

Control group: Capsule of placebo 1 g, 24 hours before nephrectomy, Made in Iran

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Dr. Mojtaba Teimoori (Resident)

Street address

Sardar Jangal Street, Razi hospital

City

Rasht

Fax

+98 13 3352 5259

Email

urc1384@yahoo.com;mojtaba_teimoori@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Urology Research Centre, Guilan University of Medical Sciences

Full name of responsible person

Dr. Siavsh Falahatkar

Street address

Sardar Jangal Street, Razi hospital, Urology Research Centre

City

Rasht

Grant name**Grant code / Reference number**

32

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Urology Research Centre, Guilan 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**

Urology Research Center

Full name of responsible person

Dr. Mojtaba Teimoori

Position

Co worker/Resident

Other areas of specialty/work**Street address**

Urology Research Center, Razi Hospital, Sardar Jangal Street

City

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Postal code

41448-95655

Phone

+98 13 3352 5259

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Urology Research Center

Full name of responsible person

Dr. Gholamreza Mokhtari

Position

Associated Proffesor of Guilan University of Medical Sciences

Other areas of specialty/work**Street address**

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Person responsible for updating data

Contact**Name of organization / entity**

Urology Research Center

Full name of responsible person

Samaneh Esmaeili

Position

Research Expert/Master

Other areas of specialty/work**Street address**

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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