Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of acid-base balance on cytokines serum level and outcome of renal transplant

Protocol summary

Summary

The aim of are study is Effect of acid-base balance on cytokines serum level and outcome of renal transplant and the accessory purposes are evaluation of Creatinine and urea during seven days after surgery in two groups and evaluation of 24 hours urine out put in two groups during seven days after surgery and evaluation of immunologic markers (cytokines serum level IL-2,IL-10,INF-y) in two groups of our study.each of two group contain of 40 patient who has End stage renal disease that aged between 18 to 70 years old candidate for renal transplant from alive donor.Exclusion criteria : Patient with sever heart disease; Metabolic Acidosis with PH < 7.15 ; Duration of operation time >3 hours ;Body temperature Axillary < 35 or >38.5 degree centigrade; requirement for transfusion ; age>70 year or <18 year ; Renal transplantation form cadaver; Unsatisfactory of patient ; History of tumor or immunology Disease ; Received immunomedullatory drug. The aim of are study is Effect of acid-base balance on cytokines serum level and outcome of renal transplant and the accessory purposes are evaluation of Creatinine and urea during seven days after surgery in two groups and evaluation of 24 hours urine out put in two groups during seven days after surgery and evaluation of immunologic markers (cytokines serum level IL-2,IL-10,INF-y) in two groups of our study.Improvement surgical condition such as correction acidosis influence to immunologic markers and outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092712203N4**
Registration date: **2016-06-02, 1395/03/13**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-06-02, 1395/03/13

Registrant information

Name
Niloufar Massoudi
Name of organization / entity
Shahid Beheshti University of Medical Science
Country
Iran (Islamic Republic of)
Phone
+98 26 3250 6961
Email address
nmasoudi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Anesthesia research center of Shahiid Beheshti University of Medical Sciences .

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of acid-base balance on cytokines serum level and outcome of renal transplant

Public title

Effect of acid-base balance on cytokines serum level and outcome of renal transplant

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Patient with End Stage Renal Disease who candidate for renal transplantation form live donor; Patient aged between 18-70 year; Patient satisfied to cooperate in this proposal. Exclusion criteria : Patient with sever heart disease; Metabolic Acidosis with PH < 7.15 ; Duration of operation time >3 hours ;Body temperature Axillary < 35 or >38.5 degree centigrade; requirement for transfusion ; age>70 year or <18 year ; Renal transplantation form cadaver; Unsatisfactory of patient ; History of tumor or immunology Disease ; Received immunomedullatory drug.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahiid Beheshtie University of Medical Sciences

Street address

Shahiid Beheshti University, Arabi Avenue , Velenjak ,Tehran .

City

Tehran

Postal code

Approval date

2016-01-03, 1394/10/13

Ethics committee reference number

IR.SBMU.RAM.REC.1394.390

Health conditions studied

1

Description of health condition studied

Renal Failure

ICD-10 code

N19

ICD-10 code description

Renal Failure

Primary outcomes

1

Description

Serum level of IFN-y

Timepoint

Befor induction of anesthesia and aftre end of surgery.

Method of measurement

Elisa Test

2

Description

Serum level of IL-2

Timepoint

Befor induction of anesthesia and aftre end of surgery.

Method of measurement

Elisa Test

3

Description

Serum level of IL10

Timepoint

Befor induction of anesthesia and aftre end of surgery.

Method of measurement

Elisa Test

Secondary outcomes

1

Description

Cratinine

Timepoint

After surgery for one week

Method of measurement

Serum Level base on labratory base

2

Description

Urine output 24 hours

Timepoint

After surgery for one week

Method of measurement

Base of urine weight

3

Description

BUN

Timepoint

After surgery for one week
Method of measurement
Serum Level base on labratory base

4

Description
Urine output 24 hours
Timepoint
After surgery for one week
Method of measurement
Base of urine weight

Intervention groups

1

Description
Control Group : same volume of Intervention Group received saline
Category
Treatment - Drugs

2

Description
Intervention Group :sodium bicarbonate base on Arterial Blood Gas Test.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Modarres Hospital
Full name of responsible person
Nilofar Massoudi
Street address
Modarres Hospital,Faraz Bollvar, Saadatabad ,Tehran.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Anesthesiology Research Center Of Shahid Beheshti University OF Medical Sciences
Full name of responsible person
Ali Dabbagh,MD
Street address
Talaghani Hospital , Arabi Avenue ,Velenjak, Tehran.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Anesthesiology Research Center Of Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Nilofar Massoudi
Position
MD/Assistant Professor
Other areas of specialty/work
Street address
Moddares Hospital , Faraz Bollvar ,Saadatabad, Tehran.
City
Tehran
Postal code
Phone
+98 22432575
Fax
Email
nilofarma@yahoo.com ; Fsafari@sbum.ac.ir; Alidabbagh@qums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University
Full name of responsible person
Nilofar Massoudi
Position
MD/Assistant professor
Other areas of specialty/work
Street address
Moddares Hospital , Faraz Bollvar ,Saadatabad, Tehran
City
Tehran
Postal code
Phone
+98 22432575
Fax
Email

nilofarma@yahoo.com; Fsafari@sbum.ac.ir; Alidabbagh@qums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University

Full name of responsible person

Navid Noraee

Position

MD / Assistanr professor

Other areas of specialty/work

Street address

Moddares Hospital , Faraz Bollvar ,Saadatabad, Tehran

City

Tehran

Postal code

Phone

+98 22432575

Fax

Email

nilofarma@yahoo.com ; Fsafari@sbum.ac.ir ; Alidabbagh@qums.ac.ir

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