

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparing fluid therapy guided by PVI (Plethysmography Variability Index) monitoring vs. conventional fluid therapy in improving transplant kidney function and blood lactate levels in kidney transplant patients

Protocol summary

Summary

In a prospective controlled double blinded clinical trial we try to find which method; PVI guided fluid therapy or conventional methods, helps keep kidney function better (as measured by urine output) and prevents acidosis from worsening (as measured by serum lactate). We select our patients from Kidney transplant recipients between 18 and 70 years old who are not cases of Known Cardiomyopathy; AF Rhythm; blood transfusion during surgery; History of valve replacement surgery; Asthma or COPD; Morbid Obesity; EF<40%, Hb<7; Symptomatic coronary artery disease and prior kidney transplantation history. Patients who develop arrhythmias during perioperative period or have a blood loss more than 1000cc are excluded from the study. We use PVI monitoring to give fluids to patients during surgery and use known conventional liberal methods for the control group. We measure Urine volumes, Serum lactate, Hemodynamic measures (heart rate and Mean arterial pressure) and ABG factors during peri-operative period and kidney function 6 months after surgery to compare the newly discovered and non-invasive PVI monitoring to conventional more liberal methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072929116N1**
Registration date: **2016-12-07, 1395/09/17**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-07, 1395/09/17

Registrant information

Name

Fardad Iranidoust Haghighi

Name of organization / entity

Tehran university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences. School of medicine

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2017-03-18, 1395/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing fluid therapy guided by PVI (Plethysmography Variability Index) monitoring vs. conventional fluid therapy in improving transplant kidney function and blood lactate levels in kidney transplant patients

Public title

Comparing fluid therapy for kidney transplant surgery guided by PVI (Plethysmography Variability Index) monitoring and conventional fluid therapy in improving transplant kidney function

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Kidney transplant recipients between 18 and 70 years old who are not cases of known cardiomyopathy; AF rhythm; Blood transfusion during surgery; History of valve replacement surgery; History of asthma or chronic obstructive pulmonary disease; Morbid obesity; EF<40%, Hb<7; Symptomatic coronary artery disease; Prior kidney transplantation history; Exclusion criteria: peri-operative arrhythmias; peri-operative blood loss more than 1000cc;

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Individuals are assigned to control and intervention group randomly via a random numbers table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University Of Medical Sciences Medical Ethics Committee

Street address

Tehran University Of Medical Sciences, Tehran, Iran

City

Tehran

Postal code

Approval date

2016-04-04, 1395/01/16

Ethics committee reference number

IR.TUMS.REC.1395.2281

Health conditions studied

1

Description of health condition studied

End Stage Renal Failure

ICD-10 code

N18.5

ICD-10 code description

End stage kidney disease on dialysis

Primary outcomes

1

Description

Urine Volume

Timepoint

Before and after aortic declamping, 2hours after surgery, The day after surgery, 6 months after surgery

Method of measurement

Reading the Urine bag value

2

Description

Serum Lactate

Timepoint

Before and after aortic declamping, 2hours after surgery, The day after surgery, 6 months after surgery

Method of measurement

Arterial Blood Gas sample

Secondary outcomes

1

Description

Serum creatine

Timepoint

before surgery, The day after surgery

Method of measurement

Biochemistry Lab test

2

Description

Blood Urea Nitrogen

Timepoint

before surgery, The day after surgery

Method of measurement

Biochemistry Lab test

3

Description

Arterial Blood Gas (ABG)

Timepoint

before surgery, before and after aortic declamp, 2hours after surgery, The day after surgery

Method of measurement

Arterial Blood Gas sampling

4

Description

Heart Rate per minute

Timepoint

before surgery, before and after aortic declamp, 2hours
after surgery, The day after surgery

Method of measurement

Pulse oximetry

5

Description

Blood Pressure (Mean Arterial Pressure)

Timepoint

before surgery, before and after aortic declamp, 2hours
after surgery, The day after surgery

Method of measurement

Non Invasive Blood Pressure monitoring

Intervention groups

1

Description

In the intervention group we use PVI monitoring (plethysmography variability index) to administer fluids during kidney transplantation surgery. We use the Masimo set PVI monitoring. Masimo, Irvine California. We use the device to guide the peri-operative fluid therapy during the surgery in the operating room. The PVI index is maintained between 10-13 by administering additional crystalloids. as the index rises above 13, 200 milliliters of crystalloids are administered and maintenance is given so that the index is always between 10 and 13. If the index is below 10, then all the crystalloids are held except half the maintenance need.

Category

Treatment - Other

2

Description

In the control group we administer fluids to the patients by the conventional liberal methods for transplant recipient patients. we give fluids freely to compensate for hemodynamic abnormalities and/or fluid loss and deficits and half the maintenance needs to the patients during surgery.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Dr. Fardad Iranidoost Haghighi

Street address

Shariati Hospital, Jalal-e-ale ahmad St, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tehran University of
Medical Sciences

Full name of responsible person

Dr. Shahin Akhonzadeh

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Poursina St. 16th Azar St. School of medicine. Tehran
University of Medical Sciences

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Tehran 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

Tehran University Of Medical Sciences

Full name of responsible person

Fardad Iranidoost Haghighi

Position

Resident of Anesthesiology

Other areas of specialty/work

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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