

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of acid-base balance on neuromuscular blockage in renal transplant

Protocol summary

Summary

Objectives Effect of acid-base balance on neuromuscular blockage in renal transplant, estimation the time of reversal of muscular blockage 3from 4 after de clump, evaluation of acidosis during the surgery and after de clump. Design study will be double blind clinical trial that each of two group contain of 15 number of patients in age between 18 to 70 who have end stage renal disease and candidate for alive donors kidney transplantation. Setting and conduct first will accumulate the demographics and clinical information of patient such as age, sex, weight, and time after last hemodialysis, time from beginning end stage renal disease and ABG (Arterial Blood Gas) basis and ABG in de clump and registration TOF(Train of forth) due to estimation of muscular relaxation from induction until the end of surgery in form. Inclusion criteria: Patient with ESRD(End stage Renal Disease) candidate for renal transplantation from live donor; patient aged between 18-70; patient satisfied to cooperate in proposal. Exclusion criteria: patient with sever heart disease; Metabolic acidosis PH<7.15; duration of operation>3 hours; Body temperature in axillary < 35 degree Centigrade or >38.5 degree centigrade; Requirement for transfusion; aged <18 or >70 year; unsatisfaction of patient. Intervention will be administration of bicarbonate and correction the acidosis. Main outcome measures (variables) will be time of reversal muscular blockage, acidosis, bicarbonate, Carbone dioxide on base of arterial blood gas.

General information

Acronym

Acidosis, Kidney Transplantation, Neuromuscular blockage .

IRCT registration information

IRCT registration number: **IRCT2015092612203N3**

Registration date: **2016-03-27, 1395/01/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-27, 1395/01/08

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 research of Anesthesiology Center
Shahid Beheshti University.

Expected recruitment start date

2015-10-21, 1394/07/29

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of acid-base balance on neuromuscular blockage
in renal transplant

Public title

Effect of acid-base balance on neuromuscular blockage
in renal transplant

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: Patient with ESRD (End stage Renal Disease) candidate for renal transplantation from live donor; patient aged between 18-70; patient satisfied to cooperate in proposal. Exclusion criteria: patient with severe heart disease; Metabolic acidosis $\text{PH} < 7.15$; duration of operation > 3 hours; Body temperature in axillary < 35 degree Centigrade or > 38.5 degree centigrade; Requirement for transfusion; aged < 18 or > 70 year; unsatisfaction of patient.

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

Gender
 Both

Phase
 1

Groups that have been masked
No information

Sample size
 Target sample size: **30**

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 Shahid Beheshti University of Medical Sciences

Street address

Kodakyar Street, Arabi Avenue, Velenjac

City

Tehran

Postal code

Approval date

2015-12-26, 1394/10/05

Ethics committee reference number

IR.SBMU.REC.1394.105

Health conditions studied

1

Description of health condition studied

End Stage Renal Disease

ICD-10 code

N17, N18, N1

ICD-10 code description

Renal Failure

Primary outcomes

1

Description

Time of reversal neuromuscular loose

Timepoint

Time between inject muscle relaxant and reversal

Method of measurement

measure with TOFSCAN

Secondary outcomes

1

Description

PH

Timepoint

During surgery

Method of measurement

Arterial Blood Gas

2

Description

HCO_3

Timepoint

During surgery

Method of measurement

Arterial Blood Gas

3

Description

CO_2

Timepoint

During surgery

Method of measurement

Arterial Blood Gas

4

Description

Base excess

Timepoint

During surgery

Method of measurement

Arterial Blood Gas

5

Description

Duration of Renal Failure

Timepoint

From the time started dialysis

Method of measurement

Measuring years

Intervention groups

1

Description

Intervention Group receive sodium bicarbonate upon the Base Excess

Category

Treatment - Drugs

2

Description

Control Group receive saline equal volume of intervention group

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

Vice Chancellor for research of Anesthesiology Center
Shahid Beheshti University

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

Vice Chancellor for research of Anesthesiology Center
Shahid Beheshti University

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

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 21 2243 2575

Fax

Email

nilofarma@yahoo.com; alidabbagh@sbmu.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; alidabbagh@sbmu.ac.ir;

Fsafari@sbmu.ac.ir.

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University

Full name of responsible person

Navid Noraei

Position

Other areas of specialty/work

Street address

Moddares Hospital , Faraz Bollvar ,Saadatabad,
Tehran

City

Tehran

Postal code

Phone

+98 22432575

Fax

Email

navidnooraee@yahoo.com ; nilofarma@yahoo.com ;

Fsafari@sbmu.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