

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of Acid-Base and Electrolytes Imbalance in Normal Saline and Bicarbonate 1/6 Molar Intravenous Fluid Infusions during Cervical and Lumbar Laminectomy: A Pilot Double-Blinded Clinical Trial

Protocol summary

Summary

This study aimed to compare electrolytes and acid-base imbalance occurrence in two fluid therapy methods using normal saline and 1/6 molar sodium bicarbonate in cervical and lumbar laminectomy surgeries. 35 to 70 years old patients with ASA class I and II, candidate for cervical and lumbar spinal laminectomy referred to Baqiyatallah Hospital in 2014 were enrolled. Patients with chronic kidney disease, hepatic failure, electrolytes imbalance, changes in blood pressure more than 30% of basal amount, needing blood transfusion before and during operation were excluded from study. Patients were randomized into two groups by a computer generalized list (20 patients in each group). Fluids needed were calculated in all patients. Maintenance fluid therapy was done using normal saline and deficit fluid therapy was done using 1/6 molar sodium bicarbonate in first group, while maintenance and deficit fluid therapies were done using normal saline in the second group. All other anesthesia processes were the same in the both group. Sodium bicarbonate 1/6 molar was produced using 150 mL sodium bicarbonate 7.5% added to 850 mL infusible distilled water identical in shape and size with normal saline fluid by another anesthesiologist. Drug prescriber, who filled the checklists in all stages as well as the person who performed the analysis were unaware of infused fluid in both groups. All patients were evaluated using arterial blood gasses, blood electrolytes levels, and hemodynamic factors before and after the operation. Collected data were compared between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014061717413N4**

Registration date: **2015-03-28, 1394/01/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-03-28, 1394/01/08

Registrant information

Name

Hamidreza Karimi-Sari

Name of organization / entity

Student Research Committee, Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8126 4354

Email address

hrkarimisari@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Baqiyatallah University of Medical Sciences, Deputy of Research

Expected recruitment start date

2014-07-11, 1393/04/20

Expected recruitment end date

2014-12-31, 1393/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Acid-Base and Electrolytes Imbalance in Normal Saline and Bicarbonate 1/6 Molar Intravenous Fluid Infusions during Cervical and Lumbar Laminectomy: A Pilot Double-Blinded Clinical Trial

Public title

Acid-Base and Electrolytes Imbalance in Normal Saline and 1/6 Molar Sodium Bicarbonate Infusions during Surgical Laminectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 35 to 70 years old patients; with ASA class I and II; candidate for cervical and lumbar spinal laminectomy. Exclusion criteria: Patients with chronic kidney disease; hepatic failure; electrolytes imbalance; changes in blood pressure more than 30% of basal amount; needing blood transfusion before and during operation.

Age

From **35 years** old to **70 years** old

Gender

Both

Phase

N/A

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

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Baqiyatallah University of Medical Sciences Ethics Committee

Street address

Baqiyatallah University of Medical Sciences, Nosrati alley, Sheikh Bahaei Street, Mollasadra Street, Vanak Square, Tehran, I.R.Iran.

City

Tehran

Postal code

Approval date

2014-02-07, 1392/11/18

Ethics committee reference number

36-4

Health conditions studied

1

Description of health condition studied

Nerve root and plexus compressions in intervertebral disc disorders

ICD-10 code

G55.1

ICD-10 code description

Nerve root and plexus compressions in intervertebral disc disorders

2

Description of health condition studied

electrolyte and acid-base imbalance

ICD-10 code

E87

ICD-10 code description

Other disorders of fluid, electrolyte and acid-base balance

Primary outcomes

1

Description

Electrolytes imbalance

Timepoint

After the surgery

Method of measurement

Electrolytes level checking in patients' blood sample

2

Description

Acid-base imbalance

Timepoint

After the surgery

Method of measurement

Arterial blood gasses levels in patients' arterial blood sample

Secondary outcomes

empty

Intervention groups

1

Description

Maintenance fluid therapy was done using normal saline and deficit fluid therapy was done using 1/6 molar sodium bicarbonate in the first group.

Category

Treatment - Drugs

2

Description

All maintenance and deficit fluid therapies were done using normal saline in the second group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Seyed Jalal Madani

Street address

Baqiyatallah Hospital, Mollasadra St., Vanak Sq., Tehran, I.R.Iran

City

Tehran

Students' Research Committee (SRC), Baqiyatallah University of Medical Sciences, Tehran, IR Iran

Full name of responsible person

Hamidreza Karimi-Sari

Position

General Practitioner

Other areas of specialty/work

Street address

Baqiyatallah University of Medical Sciences, Nosrati alley, Sheikh Bahaei Street, Mollasadra Street, Vanak Square, Tehran, I.R.Iran.

City

Tehran

Postal code

Phone

+98 21 8126 4354

Fax

+98 21 8126 4354

Email

dr.karimih@yahoo.com

Web page address

<http://bmsusrc.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Baqiyatallah University of Medical Sciences, Deputy of Research

Full name of responsible person

Seyed Jalal Madani

Street address

Baqiyatallah Hospital, Sheikh Bahaei Street, Mollasadra Street, Vanak Square, Tehran, I.R.Iran.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Baqiyatallah University of Medical Sciences, Deputy of Research

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Anesthesiology Department, Faculty of Medicine, Baqiyatallah University of Medical Sciences, Tehran,

Full name of responsible person

Seyed Jalal Madani

Position

Assistant Professor

Other areas of specialty/work

Street address

Baqiyatallah University of Medical Sciences, Nosrati alley, Sheikh Bahaei Street, Mollasadra Street, Vanak Square, Tehran, I.R.Iran.

City

Tehran

Postal code

Phone

+98 21 8126 4354

Fax

Email

dr.jalalmadani@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Students' Research Committee (SRC), Baqiyatallah University of Medical Sciences (BMSU), Tehran, Iran

Full name of responsible person

Hamidreza Karimi-Sari

Position

General Practitioner

Other areas of specialty/work

Street address

Baqiyatallah University of Medical Sciences, Nosrati

alley, Sheikh Bahaei Street, Mollasadra Street, Vanak
Square, Tehran, I.R.Iran.

City

Tehran

Postal code

Phone

+98 21 8126 4354

Fax

+98 21 8126 4354

Email

dr.karimih@yahoo.com

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