

# 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.

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##### 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.

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## Person responsible for updating data

#### Contact

##### Name of organization / entity

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##### Full name of responsible person

Hamidreza Karimi-Sari

##### Position

General Practitioner

##### Other areas of specialty/work

##### Street address

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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*