

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of intravenous fluid therapy with ISO tonic and hypo tonic fluids (saline .45%) on biochemical parameters of admitted patients to Intensive care unit

Protocol summary

Summary

The aim of this study was to evaluate the effect of intravenous fluid with ISO tonic and hypo tonic fluids on biochemical parameters of patients who were admitted in intensive care unit of Imam Sajad hospital and Behest i hospital, Yasuj, Iran in 2017. Patients over 18 years; patients who have not baseline electrolyte imbalance; were enrolled. And patients with chronic renal and heart failure; patients who have taken diuretics; patients with acute or chronic neurological disorder; patients who take sodium bicarbonate; were excluded. This clinical trial is conducted on 64 patients. Patients were NP O for at least 48 hours and vital signs and urine output were measured. Patients were randomly assigned (1.1 ratio) in to two groups and one group received normal saline and the other group received half saline. For all patients before and after treatment glucose-creation-urea-potassium-sodium-blood gases and urine specific gravity were measured and compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017101522869N5**

Registration date: **2017-11-16, 1396/08/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-16, 1396/08/25

Registrant information

Name

Moslem Sedaghattalab

Name of organization / entity

Yasuj University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 74 3322 0163

Email address

m.sedaghattalab@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Yasuj University of Medical Science

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intravenous fluid therapy with ISO tonic and hypo tonic fluids (saline .45%) on biochemical parameters of admitted patients to Intensive care unit

Public title

Effect of intravenous fluid therapy with ISO tonic and hypo tonic fluids on biochemical parameters of patients who was admitted in intensive care unit

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age > 18 years; absence of electrolyte imbalance before the study; absence of brain damage (tumor-ischemia-bleeding and etc.). Exclusion criteria:

Serum sodium <133 or>145 on admission ; patients with chronic renal failure; patients with chronic heart failure; patients who were admitted with increased blood pressure; patients who have taken diuretics; patients with edema; patients with abnormalities of the adrenal gland; patients with acute or chronic neurological disorder; Patients who take sodium bicarbonate.

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Yasuj University of Medical Science

Street address

Yasuj University of Medical Science, Motahari street, Yasuj city

City

Yasuj

Postal code

75917-41417

Approval date

2017-10-07, 1396/07/15

Ethics committee reference number

IR.YUMS.REC.1396.37

Health conditions studied

1

Description of health condition studied

electrolyte imbalance

ICD-10 code

E87.1

ICD-10 code description

Hypo-osmolality and hyponatraemia

Primary outcomes

1

Description

plasma sodium

Timepoint

48

Method of measurement

flame emission photometry

Secondary outcomes

1

Description

Hyponatremia

Timepoint

48

Method of measurement

Flame emission photometry

Intervention groups

1

Description

Patients received intravenous ISO tonic fluid

Category

Treatment - Drugs

2

Description

Patients received intravenous hypotonic fluid

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

intensiv care unit of Emam sajad and Beheshti hospital

Full name of responsible person

Moslem Sedaghattalb

Street address

Emam Sajad hospital, Dr.Jalil street, Yasuj city

City

Yasuj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Yasuj University of
Medical Sciences

Full name of responsible person

Moslem Sedaghattalab

Street address

Motahari street, Yasuj city Yasuj

City

Yasuj

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 Yasuj 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**

Yasuj University of Medical Science

Full name of responsible person

moslem Sedaghattalab

Position

Assiatant professor

Other areas of specialty/work**Street address**

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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