

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### comparing the effectiveness of the Ringer lactate vs.mixture of hypertonic saline and Ringer lactate , on hemodynamic variables in major uro-oncologist surgeries

#### Protocol summary

##### Study aim

The intraoperative hemodynamic and metabolic effects of two fluid regimens in major Uro-Oncologic surgeries.

##### Design

Two arm 27 patients, parallel group, randomized trial with double blinded perioperative fluid management assessment

##### Settings and conduct

This study will done in Urologic operating room on two separated group. In control group they receive ringer lactate for perioperative fluid management and in case group, they take a mixture of ringer lactate and hypertonic saline. the patient and anesthetic nurse who will infuse the fluid would not inform the type of groups.

##### Participants/Inclusion and exclusion criteria

. Inclusion criteria: patients with ASA $\leq$  III who were scheduled for major Uro-Oncologic surgeries. Exclusion criteria: GFR<45 ml/min.

##### Intervention groups

Control group: Intra operative fluid management with Ringer lactate Case group: Intra operative fluid management with the mixture of ringer lactate and hypertonic saline

##### Main outcome variables

Hemodynamic conditions; Electrolytes; Arterial Blood Gas;

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150116020676N3**

Registration date: **2019-01-10, 1397/10/20**

Registration timing: **prospective**

Last update: **2019-01-10, 1397/10/20**

Update count: **0**

##### Registration date

2019-01-10, 1397/10/20

##### Registrant information

###### Name

Farhad Tavakoli

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2226 9950

###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-01-21, 1397/11/01

##### Expected recruitment end date

2019-07-23, 1398/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

comparing the effectiveness of the Ringer lactate vs.mixture of hypertonic saline and Ringer lactate , on hemodynamic variables in major uro-oncologist surgeries

##### Public title

The effect of hypertonic saline in intraoperative fluid management

##### Purpose

Treatment

IR.TUMS.IKHC.REC.1396.3724

## Inclusion/Exclusion criteria

### Inclusion criteria:

all patients with ASApSI-III who scheduled for major Uro-Oncologic surgeries

### Exclusion criteria:

GFR<45 ASApS >3 patients refusal

## Age

From 18 years old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Data analyser

## Sample size

Target sample size: 54

## Randomization (investigator's opinion)

Randomized

## Randomization description

According random 4 BLOCK that will make by excel software .

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

Patient how entered this study would not inform about the type of fluid management. The anesthetic nurse don't have information about the fluid using for fluid management during the study

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

##### Street address

Imam Khomeini Hospital, Keshavariz Blvd.

##### City

Tehran

##### Province

Tehran

##### Postal code

14197-33141

#### Approval date

2017-10-16, 1396/07/24

#### Ethics committee reference number

## Health conditions studied

### 1

#### Description of health condition studied

Intraoperative Fluid management

#### ICD-10 code

E87

#### ICD-10 code description

Other disorders of fluid, electrolyte and acid-base balance

## Primary outcomes

### 1

#### Description

Mean Arterial Pressure, Central Vein Pressure

#### Timepoint

Mean arterial pressure and central vein pressure were evaluated during surgery continuously.

#### Method of measurement

Digital Blood Pressure Monitor

## Secondary outcomes

### 1

#### Description

Electrolytes, Arterial blood Gas

#### Timepoint

Hourly

#### Method of measurement

Nova plus-M,U.S.A lab kits

## Intervention groups

### 1

#### Description

Intervention group: In this group, the mixture of hypertonic saline and ringer lactate will use for intraoperative fluid management.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Complex Hospital Urology Operating Room

##### Full name of responsible person

Hosein Gholami

##### Street address

Imam Khomeini Hospital, Keshavariz Blvd.

##### City

Tehran  
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Dr.ghlami65@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Shahin Akhond zadeh M.D  
**Street address**  
Imam Khomeini Hospital, Keshavariz Blvd.  
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Dr.ghlami65@gmail.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Tehran University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
HamidReza Amiri  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**

Anesthesiology  
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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Hosein Gholami  
**Position**  
Anesthetics Residence  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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## Person responsible for updating data

#### Contact

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**Full name of responsible person**  
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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

Nameless of patients data will be demonstrate, when this study got completed

**When the data will become available and for how long**

Access to these data will allowable 3 month after publishing.

**To whom data/document is available**

It is only accessible for academic and scientific organs.

**Under which criteria data/document could be used**

Analysis of these data are allowable

**From where data/document is obtainable**

Hosein gholami M.D Dr.ghlami65@gmail.com  
00982161192828

**What processes are involved for a request to access data/document**

In one month data will accessible.

**Comments**