

# 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

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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

**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

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Imam Khomeini Hospital, Keshavariz Blvd.

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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  
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Imam Khomeini Hospital, Keshavariz Blvd.  
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**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

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Hosein Gholami  
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Anesthetics Residence  
**Latest degree**  
Medical doctor  
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## Person responsible for updating data

#### Contact

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**Email**

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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**