# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Jun 2026

## Comparison effect of two approach for Improvement of patients Conditions in Recovery Using of oral or interavenous Glucose Pretreatment in Laparotomy surgeries

## Protocol summary

**Study aim**
Comparison effect of oral or intravenous glucose pretreatment for improvement of recovery stay compared with control group

**Design**
In this double-blind randomized controlled clinical trial, faze 3 study with parallel groups, 90 patients undergoing laparotomy were randomly divided into 3 groups of 30 divided into the first group of intravenous glucose, the oral glucose guided group and the third group (control group) oral normal saline, 6 hours after fasting preoperatively were prescribed and recovery conditions were compared in three groups.

**Settings and conduct**
This study was carried out on patients undergoing laparotomy in Alzahra hospital in Isfahan in 1399. This study is done in two sucrose methods. Patients are unaware of the type of solution they are given and no explanation is given about the type of solution being given or injected. The solution is also prescribed by the patient's presenter, but the information is collected by an operating room staff who is not in the study.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria:: Patients are candidates for laparotomy surgery, age range 18 to 65 years, physical health status 1 and 2. Non-entry criteria: Patients with diabetes and reflex, patients who need to take anti emetic drugs before surgery.

**Intervention groups**
In this study 90 patients undergoing laparotomy were divided into 3 groups of 30 each. All three groups received 10 ml/kg of serum 1/3-2/3 at the time of preoperative fasting, and 6 hours later, the first group received 1 g / kg glucose in 50 ml of normal saline intravenously injections, the second group 1 g / kg glucose in 50 Ml of saline orally and the third group receive 50 ml of normal saline orally.

**Main outcome variables**
Postoperative pain, length of stay in recovery, nausea, vomiting

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20130311012782N55**
Registration date: **2021-07-10, 1400/04/19**
Registration timing: **retrospective**

Last update: **2021-07-10, 1400/04/19**
Update count: **0**

**Registration date**
2021-07-10, 1400/04/19

**Registrant information**

**Name**
Ali Mehrabi kushki

**Name of organization / entity**
Isfahan University of Medical Sciences

**Country**
Iran (Islamic Republic of)

**Phone**
+98 31 3629 1510

**Email address**
mehrabi@mui.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-08-22, 1399/06/01

**Expected recruitment end date**
2021-03-18, 1399/12/28

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison effect of two approach for Improvement of patients Conditions in Recovery Using of oral or interavenous Glucose Pretreatment in Laparotomy surgeries

**Public title**

Comparison effect of oral glucose administration and preoperative injection on patient status in recovery

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patient undergoing laparotomy Patient's consent to participate in the study American Society of Anesthesiologists(ASA) : 1 or 2

**Exclusion criteria:**

Body Mass Index 30 or above diabetes reflux Requires preoperative Antiemetic medication

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization of patients is done using Random Allocation Aoft ware(RAS). The total sample size (90 people) is entered into the software and then the number of study groups (3 groups) is determined. The software output contains a list that distributes numbers 1 to 90 randomly in three columns. Patients are divided into groups according to the time list of admission to the hospital to reach the required sample size in each group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This study is a double blind study. Patients are unaware of the type of solution they receive. The solution used by the researcher is also prescribed for patients, but the information is collected by one of the operating room personnel who is unaware of the type of solution being received.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

**Street address**

Research faculty, Isfahan University of Medical Sciences, Hezarjerib street

**City**

Isfahan

**Province**

Isfehan

**Postal code**

8434193474

**Approval date**

2019-02-09, 1397/11/20

**Ethics committee reference number**

IR.MUI.MED.REC.1398.010

## Health conditions studied

### 1

**Description of health condition studied**

Recovery condition

**ICD-10 code**

K91.86

**ICD-10 code description**

cholecystectomy

## Primary outcomes

### 1

**Description**

post operative pain

**Timepoint**

during recovery stay

**Method of measurement**

Visual Analog Scale

### 2

**Description**

stay in recovery time

**Timepoint**

End of recovery

**Method of measurement**

Calculates the time interval of entry to exit recovery in minutes

### 3

**Description**

nausea

**Timepoint**
During recovery stay
**Method of measurement**
Ask the patient

**4**

**Description**
Vomitting
**Timepoint**
During recovery stay
**Method of measurement**
Ask the patient

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group 1: 10 ml/ kg of serum 1/3-2/3 at first fasting and after 6 hours, 1 g / kg glucose dissolved in 50 ml of normal saline is injected intravenously.
**Category**
Prevention

**2**

**Description**
Intervention group 2: 10 ml/ kg of serum 1/3-2/3 at first fasting and after 6 hours, 1 g / kg glucose dissolved in 50 ml of normal saline is orally prescribed.
**Category**
Prevention

**3**

**Description**
Control group: 10 ml/ kg of serum 1/3-2/3 at first fasting and after 6 hours, 50 ml of normal saline is orally prescribed.
**Category**
Prevention

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Alzahra hospital
**Full name of responsible person**
Ladan Salehfard
**Street address**
Department of Anesthesiology, Alzahra hospital, Soffeh street
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8434193474
**Phone**
+98 31 3668 5555
**Email**
ladan.salehfard@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Shaghayegh Haghjoo
**Street address**
Research faculty, Isfahan University of Medical Sciences, Hezarjerib street
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8434193474
**Phone**
+98 31 3792 3070
**Email**
sh_haghjoo@med.mui.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Esfahan 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**
Esfahan University of Medical Sciences
**Full name of responsible person**
Taghi Hashemi
**Position**
Assistant professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Anesthesiology
**Street address**

Department of anesthesiology, Alzahra hospital, Soffeh street

**City**
Isfahan

**Province**
Isfehan

**Postal code**
8434193474

**Phone**
+98 31 3668 5555

**Email**
st_hashemi@med.mui.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Esfahan University of Medical Sciences

**Full name of responsible person**
Mitra Jabalameli

**Position**
Associate professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Anesthesiology

**Street address**
Department of Anesthesiology, Alzahra hospital, Soffeh street

**City**
Isfahan

**Province**
Isfehan

**Postal code**
8434193474

**Phone**
+98 31 3668 5555

**Email**
Jabalameli@med.mui.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Esfahan University of Medical Sciences

**Full name of responsible person**
Ali Mehrabi

**Position**
Statistical Consultant

**Latest degree**
Master

**Other areas of specialty/work**
Epidemiology

**Street address**
Research faculty, school of medicine, Isfahan University of Medical Sciences, Hezarjerib street

**City**
Isfahan

**Province**
Isfehan

**Postal code**
8434193474

**Phone**
0098 31 3728081

**Email**
al.mehrabi@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**
The project is owned by the state agency and cannot be published.

**Study Protocol**
No - There is not a plan to make this available

**Statistical Analysis Plan**
No - There is not a plan to make this available

**Informed Consent Form**
No - There is not a plan to make this available

**Clinical Study Report**
No - There is not a plan to make this available

**Analytic Code**
No - There is not a plan to make this available

**Data Dictionary**
No - There is not a plan to make this available