

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison abdominal washing in patients with acute peritonitis using “normal saline solution with trolls” compared with “normal saline solution”

#### Protocol summary

##### Study aim

The aim is Comparison abdominal washing in patients with acute peritonitis using “normal saline solution with trolls” compared with “normal saline solution”.

##### Design

This assessment is a clinical trial in phase 3; neonates who are diagnosed with peritonitis are considered as study group. In this study, 20 patients with inclusion criteria are selected. Patients are randomly assigned to the blockade method, 10 patients in normal lavage with normal saline and 10 patients in normal lavage with normal saline and trolls group. Accordingly, after surgery, the signs and symptoms associated with peritonitis are evaluated.

##### Settings and conduct

This study was carried out as a clinical trial at the Shohaday Khaliye Fars Hospital in Bushehr, Also the study will be single blinded in which patients will be blinded in study.

##### Participants/Inclusion and exclusion criteria

Patients with peritonitis aged 15 to 65 years are included in the study as well as patients with evidence of intestinal encephalopathy, liver and kidney disease, history of steroid use, history of hypersensitivity and allergy to substances containing citrate, multiple trauma and organ damage in the event of vascular rupture and pregnancy are excluded from the study.

##### Intervention groups

In the intervention group, abdominal lavage was performed using normal saline and trolls and in the control group, abdominal lavage was done by normal saline.

##### Main outcome variables

Signs and Symptoms of Peritonitis

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190304042923N1**

Registration date: **2019-03-15, 1397/12/24**

Registration timing: **retrospective**

Last update: **2019-03-15, 1397/12/24**

Update count: **0**

##### Registration date

2019-03-15, 1397/12/24

##### Registrant information

##### Name

mohammad amin rezari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 5364 2934

##### Email address

rezaei@bpums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-05, 1397/01/16

##### Expected recruitment end date

2018-10-08, 1397/07/16

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison abdominal washing in patients with acute peritonitis using "normal saline solution with trolls" compared with "normal saline solution"

## Public title

Evaluation effect of abdominal washing in patients with acute peritonitis using normal saline solution with trolls

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Acute Peritonitis Age more than 15 years and under 65 years

### Exclusion criteria:

enteric encephalopathy Liver disease kidney Diseases History of steroid use History of allergy and allergic to citrate-containing substances Multiple trauma and organ damage in case of vascular rupture Pregnancy

## Age

From **15 years** old to **65 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant

## Sample size

Target sample size: **20**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In order to randomization we will use the block method, Accordingly, the patients under study are divided into two groups. The allocation of patients in two groups was based on demographic characteristics and their matching. Based on this, after considering the patients' demographic data, patients were divided into two equal groups of patients, they enrolled in the study and performed desired intervention on them.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

This means that patients in groups do not know the used drugs, and drugs has similar packaging.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

Ethics committee of Bushehr University of Medical Sciences

#### Street address

Bushehr Province, Bandar Bushehr, Kuy-e-Bandar, Moallem St. Iran

#### City

Bushehr

#### Province

Boushehr

#### Postal code

7518759577

#### Approval date

2019-03-01, 1397/12/10

#### Ethics committee reference number

IR.BPUMS.REC.1397.123

## Health conditions studied

### 1

#### Description of health condition studied

Peritonitis

#### ICD-10 code

K65

#### ICD-10 code description

Peritonitis

## Primary outcomes

### 1

#### Description

Peritonitis

#### Timepoint

After the surgery

#### Method of measurement

According to the general state, the respiratory state, the symptoms of local infection, symptoms of systemic infection, heart rate, respiratory rate, blood loss, body temperature, wound healing, suture location, infection, abdominal sign and symptom, as well as abdominal abscesses is examined by ultrasound or CT scan if necessary.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In this group, abdominal lavage is used by normal saline and trolls.

#### Category

Treatment - Surgery

### 2

#### Description

Control group: In this group, abdominal lavage is used by

normal saline.

**Category**

Treatment - Surgery

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Shohaday Khalije Fars Hospital

**Full name of responsible person**

Mohammad Amin Rezaei

**Street address**

Pardis Blvd, University Blvd.

**City**

Bushehr

**Province**

Boushehr

**Postal code**

7518759577

**Phone**

+98 76 3367 0280

**Email**

rezaei@bpums.ac.ir

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Boushehr University of Medical Sciences

**Full name of responsible person**

Gholamreza Khamisipour

**Street address**

Bushehr University Of Medical Sciences

**City**

Bushehr

**Province**

Boushehr

**Postal code**

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**Phone**

+98 77 1455 2247

**Email**

Ghr.Khamisi@Gmail.Com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Boushehr 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**

Boushehr University of Medical Sciences

**Full name of responsible person**

Mohammad Amin Rezaei

**Position**

Resident of Surgery

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Surgery

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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

**Study Protocol**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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