

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Clinical trials of normal saline with normal saline plus antibiotic in abdominal lavage in secondary peritonitis

Protocol summary

Summary

Objectives: The current study will aim to compare abdominal lavage with normal saline and normal saline plus antibiotic (gentamicin) in secondary peritonitis.

Design: This is a triple-blind, randomized clinical trial.

Setting and conduct: This study will perform at the Baqiyatallah University of Medical Sciences. In this study, the patients, measuring the outcomes of study participants (researchers) or Data Monitoring Committee (analyzers) of the patients unaware about intervention. Patients in both groups will divide randomly using a table of random numbers. Count of Bacteria is another outcome in this study and assess using the laboratory. This clinical trial is a phase 3 study. Major Inclusion and Exclusion criteria: Inclusion criteria: patients with the diagnosis of secondary peritonitis that have age between 15 to 60 years will undergo for urgent laparotomy were included. Exclusion Criteria: A history of allergy to gentamicin, normal saline; history of kidney disease, dialysis, hemodialysis, uncontrolled hypertension; evidence of infection at or adjacent to the operative site; and the perceived inability to follow the patient's course postoperative; patients with peritoneal carcinomatosis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092529818N1**

Registration date: **2016-10-30, 1395/08/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-30, 1395/08/09

Registrant information

Name

Shahram Manoochehry

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8805 3766

Email address

shahram.manoochehry@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Baqiyatallah University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trials of normal saline with normal saline plus antibiotic in abdominal lavage in secondary peritonitis

Public title

Comparison of normal saline with normal saline plus antibiotic in abdominal lavage in secondary peritonitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with the diagnosis of secondary peritonitis that have age between 15 to 60 years will undergo for urgent laparotomy were included. Exclusion criteria: A history of allergy to gentamicin,

normal saline; history of kidney disease, dialysis, hemodialysis, uncontrolled hypertension; evidence of infection at or adjacent to the operative site; and the perceived inability to follow the patient's course postoperative; patients with peritoneal carcinomatosis.

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baqiyatallah University of Medical Sciences

Street address

Postal code: 1435917541, Mollasadra, St - Sheikh Bahaee, St, Tehran

City

Tehran

Postal code

1435917541

Approval date

2015-09-23, 1394/07/01

Ethics committee reference number

IR.BMSU.REC.1394.171

Health conditions studied

1

Description of health condition studied

peritonitis

ICD-10 code

K65.0

ICD-10 code description

Acute peritonitis

Primary outcomes

1

Description

Infection

Timepoint

One and two weeks after operation

Method of measurement

Medical evaluation

Secondary outcomes

1

Description

Recurrence

Timepoint

One and two weeks after operation

Method of measurement

Medical evaluation

Intervention groups

1

Description

Intervention 1: normal saline and antibiotics gentamicin, gentamicin 240 mg per 500 mL of saline once during surgery. Normal saline containing 9.0 g of salt per liter (0.90%) and gentamicin formula is C21H43N5O7. How to use: At the end of surgery, a stomach lavage with antibiotic gentamicin 240 mg per 500 ml of normal saline will be given 5 minutes later, the solution is removed from the patient's abdomen. Brand of Saline and gentamicin are Saline and gentamicin.

Category

Treatment - Drugs

2

Description

Intervention 2: normal saline, per 500 mL of saline once during surgery. Normal saline containing 9.0 g of salt per liter (0.90%). How to use: At the end of surgery, a stomach lavage with antibiotic gentamicin per 500 ml of normal saline will be given 5 minutes later, the solution is removed from the patient's abdomen. Brand of Saline is Saline.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Surgery Department of Baqiyatallah hospital

Full name of responsible person

Sahram Manoochehry

Street address

Postal code: 1435917541, Mollasadra Street, Sheikh
Bahaee St, Tehran

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shahram.manoochehry@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Baqiyatallah University of Medical Sciences

Full name of responsible person

Shahram Manoochehry

Position

Faculty member/General surgery

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

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Baqiyatallah University
of Medical Sciences

Full name of responsible person

Hamid Reza Rasouli

Street address

Postal code: 1435917541, Mollasadra Street, Sheikh
Bahaee Street, Tehran

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Tehran

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, Baqiyatallah 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**

Baqiyatallah University of Medical Sciences

Full name of responsible person

Shahram Manoochehry

Position

Faculty member/General surgery

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