Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
City
Tehran

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
City
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
Postal code: 1435917541, Mollasadra Street, Sheikh Bahaee Street, Tehran
City
Tehran
Postal code
1435917541
Phone
+98 21 8805 3766
Fax
Email
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
Postal code: 1435917541, Mollasadra Street, Sheikh Bahaee Street, Tehran
City
Tehran
Postal code
1435917541
Phone
+98 21 8805 3766
Fax
Email
shahram.manoochehry@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Baqiyatallah University of Medical Sciences
Full name of responsible person
Sahahram Manoochehry
Position
Faculty member/General surgery
Other areas of specialty/work
Street address
Postal code: 1435917541, Mollasadra Street, Sheikh Bahaee Street, Tehran
City
Tehran
Postal code
1435917541
Phone
+98 21 8805 3766
Fax
Email
shahram.manoochehry@yahoo.com
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