Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of Gentamicin and Mupirucine ointments on the rate of peritonitis and exit site infection in peritoneal dialysis

Protocol summary

Summary

The purpose of this study is to compare Gentamicin and Mupirucine ointment on the rate of peritonitis and the exit site infection in peritoneal dialysis. In this study, 120 patients who were on peritoneal dialysis for at least three months, did not receive systemic antibiotics in 30 days prior to the study, and without skin hypersensitivity to Gentamicin or Mupirucine were recruited after obtaining consent. The patients who were on hemodialysis or received transplantation were excluded. The patients received either Gentamicin 0.1% ointment or Mupirocine 2% ointment, manufactured Sinadaru pharmaceutical company, for 6 months. Frequency of peritonitis and catheter exit site infection rates were evaluated at the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012282417N5**
Registration date: **2011-01-25, 1389/11/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-01-25, 1389/11/05

Registrant information

Name

Firouzeh Moeinzadeh

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1625 5555

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

Expected recruitment start date

2009-08-23, 1388/06/01

Expected recruitment end date

2010-02-20, 1388/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Gentamicin and Mupirucine ointments on the rate of peritonitis and exit site infection in peritoneal dialysis

Public title

Comparison of Gentamicin and Mupirucine ointments on the rate of peritonitis and exit site infection in peritoneal dialysis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age at least 18 years, at least 3 months on peritoneal dialysis, Satisfaction to participate in the study, lack of cutaneous hypersensitivity to gentamicin or Mupirocine ointments, Not receiving systemic antibiotics during the 30 days prior to the study
Exclusion criteria: systemic antibiotic treatment during the study, changing in dialysis route, transplantation or death, no satisfaction

Age

From **18 years** old to **99 years** old

Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences
City
Isfahan
Postal code
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
388335

Health conditions studied

1

Description of health condition studied
End stage renal disease
ICD-10 code
N18.0
ICD-10 code description
End-stage renal disease

Primary outcomes

1

Description
Rate of peritonitis
Timepoint
monthly
Method of measurement
clinical symptoms and direct inspection of dialysis fluid

Secondary outcomes

1

Description
Raete of exit site infection
Timepoint
monthly
Method of measurement
clinical symptoms

Intervention groups

1

Description
Gentamicin 0.1% ointment daily on the catheter exit site of peritoneal dialysis for 6 months
Category
Treatment - Drugs

2

Description
Mupirocine 2% ointment daily on the catheter exit site of peritoneal dialysis for 6 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital peritoneal dialysis center
Full name of responsible person
Mrs Karimi
Street address
Isfahan. Sofe Ave. Alzahra hospital
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Isfahan University of Medical Sciences
Full name of responsible person
Vice Chancellor
Street address
Isfahan. Isfahan University of Medical Science
City
Isfahan
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, Isfahan 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
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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