Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of propolis on the incidence of peritonitis in patients on continuous ambulatory peritoneal dialysis

Protocol summary

Study aim
To determine the effect of propolis on rate of peritonitis due to catheter in continuous peritoneal dialysis.

Design
Clinical Trial, by using block randomization, the Patients enter in intervention, control, or placebo group. Parallel groups, double blind.

Settings and conduct
A study is conducted in Tehran's Shafa Hospital. Propolsis ointment is provided as a blind to a dialyser. Also the data analyst is blind. The patient will be assessed every two weeks for peritoneal dialysis. Monthly and with signs of infection and peritonitis, the culture of the catheter exit site and the dialysis output fluid will be sent for 6 months.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged 18-60 years; at least history of three months peritoneal dialysis; lack of acute infections; at least 2-4 sessions of peritoneal dialysis per day; and lack of history of hypersensitivity to honey. Exclusion criteria: Other infections; catheter exit site infection; tunnel infection or peritonitis in the previous month; antibiotic therapy in the past four weeks; carriers of staphylococcus aureus; history of psychiatric illness and cognitive disorder.

Intervention groups
Intervention group: Every other day; in the morning after the dialysis the site of the catheter is washed with 0.9% normal saline and then 10% of the propolis ointment is used for 6 months. Control group: Every other day; in the morning after the dialysis the site of the catheter is washed with 0.9% normal saline and then 2% Mupirocin ointment is used for 6 months. In the placebo group: The catheter site was rinsed with 0.9% normal saline for 6 months.

Main outcome variables
Peritonitis is evaluated in the presence of Cloudy fluid, abdominal pain, white blood cell count of more than 100/ mm3 (at least 50% neutrophils), fever, and positive fluid dialysis culture.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110427006318N10**
Registration date: **2019-01-17, 1397/10/27**
Registration timing: **prospective**

Last update: **2019-01-17, 1397/10/27**
Update count: **0**

Registration date
2019-01-17, 1397/10/27

Registrant information

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Monir Nobahar
Name of organization / entity
Semnan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-04, 1397/11/15

Expected recruitment end date
2020-07-05, 1399/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of propolis on the incidence of peritonitis in patients on continuous ambulatory peritoneal dialysis

Public title
The effect of propolis on the incidence of peritonitis in patients on continuous ambulatory peritoneal dialysis

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged 18-60 years At least history of three months peritoneal dialysis Lack of acute infections At least 2-4 sessions of peritoneal dialysis per day Lack of history of hypersensitivity to honey

Exclusion criteria:
Other sites of infections Catheter exit site infection Tunnel infection or peritonitis in the previous month Antibiotic therapy over the past four weeks Carriers of staphylococcus aureus History of psychiatric illness Cognitive disorder

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
The research sample assigned to the groups of the study by permuted blocks randomization. Also blocking is used within age and frequency of dialysis during the day strata.

Blinding (investigator's opinion)
Double blinded

Blinding description
Propolsis ointment is provided as a blind to a dialyser. Also the data analyst is blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Semnan University of Medical sciences

Street address
Semnan University of Medical Sciences, Basij Blv, Semnan

City
Semnan

Province
Semnan

Postal code
3513138111

Approval date
2018-11-20, 1397/08/29

Ethics committee reference number
Ir.SEMUMS.REC.1397.200

Health conditions studied

1

Description of health condition studied
Peritonitis

ICD-10 code
K65.0

ICD-10 code description
Generalized (acute) peritonitis

Primary outcomes

1

Description
Peritonitis is evaluated in the presence of Cloudy fluid, abdominal pain, white blood cell count of more than 100/mm3 (at least 50% neutrophils), fever, and positive fluid dialysis culture.

Timepoint
The patient will be assessed every two weeks for peritoneal dialysis. An aliquot of peritoneal effluent and a swab of exit site will be sent for culture monthly and in occasion of appearance of exit site secretion or peritonitis. The duration of assessment will continue for 6 months.

Method of measurement
Symptoms of peritonitis are evaluated according to the International Society for Peritoneal Dialysis (ISPD) criteria.

Secondary outcomes

1

Description
Exit site of catheter and tunnel are monitored for signs of infection (redness, pain, warmness and swelling, secretion from the exit site of the catheter).

Timepoint
The patient will be assessed every two weeks for

infection signs. Monthly and with signs of infection and peritonitis, the culture of the catheter exit site and the dialysis output fluid will be sent for 6 months.

Method of measurement

Inspection of redness, pain, warmness and swelling, secretion from the exit site of the catheter

Intervention groups

1

Description

Intervention group: Every other day; in the morning after the dialysis the site of the catheter is washed with 0.9% normal saline and then 10% of the propolis ointment is used for 6 months.

Category

Prevention

2

Description

Control group: Every other day; in the morning after the dialysis the site of the catheter is washed with 0.9% normal saline and then 2% Mupirocin ointment is used for 6 months.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa hospital

Full name of responsible person

Monir Nobahar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Monir Nobahar

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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
Data is confidential.

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

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Data is confidential.

When the data will become available and for how long
It was possible to publish the paper from the study.

To whom data/document is available
Research group

Under which criteria data/document could be used
After publishing the resulting paper, it can be made available to others in order to use the results of the study.

From where data/document is obtainable
An article published in an valid journal among available journals

What processes are involved for a request to access data/document
The process of publishing an article in the journal

Comments