# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 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**

**Name**
Monir Nobahar
**Name of organization / entity**
Semnan University of Medical Sciences
**Country**
Iran (Islamic Republic of)
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Nobahar43@Yahoo.com

**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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Semnan, University of Medical Sciences, Nursing and Midwifery

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Parviz Kokhaei

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Semnan University of Medical Sciences, Basij Blv, Semnan

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**Phone**

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**Email**

P_kokha@yahoo.com

**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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**