# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Evaluation of the effect of increased blood flow velocity compared with administration of activated charcoal suspension on severity of uremic pruritus in hemodialysis patients

## Protocol summary

**Study aim**

Determination and Comparison of the Effect of Increasing of pamp rounds and Administration of Sharcol on Severe of Uremic Pruritus in Hemodialysis Patients

**Design**

Clinical trials are cross-over, without blindness, randomized

**Settings and conduct**

In this study, 60 patients with uremic pruritus who Referred to hemodialysis department of Imam Hossein Shahroud Hospital , will be randomly assigned to three groups A, B and C.According to the type of study for group A in the first period of first intervention,Group B is the second intervention and Group C is assihned a third intervention.After two weeks, the desired result is measured and one week wash out is considered .In the second and third period, interventions were arranged.

**Participants/Inclusion and exclusion criteria**

Be entry: orientation to the time, place, and person when collecting data At least one month of uremic pruritus Patient diagnosed with chronic renal failure Under hemodialysis for at least 6 months Perform hemodialysis three times a week for at least three hours Proper vascular access Determine the patient's dry weight no entry: There is a skin rash causing itching The presence of liver and biliary disease Unwillingness to cooperate at each stage of the research Blood pressure less than 60/100 mm Hg Maladaptation or any digestive problem

**Intervention groups**

The present study is a cross-over clinical trial with three groups and three periods and three sequences.First intervention: Increasing blood flow rate to the hemodialysis machin for two weeks .Second Intervention:Daily administration of 6 grams of activated charcoal suspension for two weeks .Third intervention: Administer 6 grams of activated charcoal suspension per day and change the same pump as the first intervention for two weeks.

**Main outcome variables**

pation pruritus

## General information

**Reason for update**

**Acronym**

CKD.chronoc kidny disease ESRD. end stage renal disease

**IRCT registration information**

IRCT registration number: **IRCT20180807040729N1**
Registration date: **2018-10-25, 1397/08/03**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-25, 1397/08/03**
Update count: **0**

**Registration date**

2018-10-25, 1397/08/03

**Registrant information**

**Name**

mahmoud zanganeh ghasemabadi

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2018-09-23, 1397/07/01

**Expected recruitment end date**

2019-03-16, 1397/12/25

**Actual recruitment start date**
2018-09-23, 1397/07/01
**Actual recruitment end date**
2019-03-16, 1397/12/25
**Trial completion date**
empty

**Scientific title**
Evaluation of the effect of increased blood flow velocity compared with administration of activated charcoal suspension on severity of uremic pruritus in hemodialysis patients

**Public title**
comparative study on the increase of blood flow velocity and administration of oral activated charcoal on the severity of uremic pruritus in hemodialysis patients
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Be alert to the time, place, and individuals when collecting information At least one month of uremic proritus Patient diagnosed with chronic renal failure Under hemodialysis for at least 6 months Perform hemodialysis three times a week for at least three hours Proper vascular access Determine the patient's dry weight
**Exclusion criteria:**
There is a skin rash causing itching The presence of liver and biliary disease Unwillingness to cooperate at each stage of the research Blood pressure less than 60/100 mm Hg Malnutrition or any digestive problem
**Age**
No age limit
**Gender**
Both

**Phase**
3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Patients were randomly assigned 6 blocks to 3 groups of 1, 2, 3 (each group of 20) using the software. using the darkened and packed envelope, the dedicated sequence is hiding.
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Crossover
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Shahroud University of Medical Sciences
**Street address**
Shahroud University of Medical Sciences, Hafte-Tir Sq., Tehran Street
**City**
shahroud
**Province**
Semnan
**Postal code**
3614773955
**Approval date**
2018-09-05, 1397/06/14
**Ethics committee reference number**
iR.SHMU.REC.1397.II8

## Health conditions studied

### 1

**Description of health condition studied**
Uremic pruritus in hemodialysis patients
**ICD-10 code**
L29.8
**ICD-10 code description**
Other pruritus

## Primary outcomes

### 1

**Description**
The incidence of itching according to the score of the questionnaire Yosipovich
**Timepoint**
The questionnaire will be completed in six steps:1- Before intervention in each group 2- Immediately after the first intervention in a triple group (first period) 3- After the first wash out in the first period 4- Immediately after the interventions defined in the second period 5. After the second wash out 6. Immediately after the interventions defined in the third period.
**Method of measurement**
The severity of itching will be measured using the Yosipovich questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
In this cross-over study, three therapeutic interventions

are compared in three groups.In other words, all three groups will receive these three interventions cross-over.(And each intervention is considered as the control group for further interventions)and therefore does not need a separate control group(placebo) First intervention: increased blood flow rate in hemodialysis machine,In the first week of intervention, the dose was 25 ml / min and in the second week it was 50 ml, compared to the standard speed(4 ml per kg body weight). Second Intervention: Daily administration of 6 grams of activated charcoal suspension for two weeks.Third intervention: Administer 6 grams of activated charcoal suspension per day and change the same with the first intervention for two weeks.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Imam Hossien hospital

**Full name of responsible person**

Dr.Hossein ebrahimi

**Street address**

end of 28-meter Touhidi, Imam Khomeini Street

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad-Hassan Emamian

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emamian@shmu.ac.ir

**Web page address**

http://research.shmu.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shahroud 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**

Shahroud University of Medical Sciences

**Full name of responsible person**

Dr Hossein ebrahimi

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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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**

No more information.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available