

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 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 pump 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 assigned 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 machine 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

pruritus

#### General information

##### Reason for update

##### Acronym

CKD.chronic kidney 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3220 0371

##### Email address

zanganeh@shmu.ac.ir

##### 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 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

**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

**City**

shahroud

**Province**

Semnan

**Postal code**

3614773955

**Phone**

+98 23 3234 2000

**Fax**

+98 23 3233 3902

**Email**

h\_ebrahimi43@yahoo.com

### Sponsors / Funding sources

#### 1

##### Sponsor

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad-Hassan Emamian

**Street address**

Shahroud University of Medical Sciences, Hafte-Tir Sq., Tehran Street

**City**

shahroud

**Province**

Semnan

**Postal code**

6314773955

**Phone**

+98 23 3239 5054

**Email**

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

**Street address**

Shahroud University of Medical Sciences, Hafte-Tir Sq., Tehran Street

**City**

shahroud

**Province**

Semnan

**Postal code**

6314773955

**Phone**

+98 23 3239 3811

**Email**

h\_ebrahimi43@yahoo.com

### Person responsible for scientific 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  
**Street address**  
Shahroud University of Medical Sciences, Hafte-Tir  
Sq., Tehran Street  
**City**  
shahroud  
**Province**  
Semnan  
**Postal code**  
3617753917  
**Phone**  
+98 23 3239 3811  
**Email**  
h\_brahim43@yahoo.com

## Person responsible for updating data

### 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  
**Street address**  
Shahroud University of Medical Sciences, Hafte-Tir

Sq., Tehran Street  
**City**  
shahroud  
**Province**  
Semnan  
**Postal code**  
36147753917  
**Phone**  
+98 23 3239 3811  
**Email**  
h\_brahim43@yahoo.com

## 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