

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Effect of Increased Dialysis Adequacy Measured by Kt/V index on Uremic Pruritus in Hemodialysis Patients of Imam Khomeini Hospital in 2012

#### Protocol summary

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##### Summary

Aim: to study the effects of increased dialysis adequacy measured by Kt/V on uremic pruritus Inclusion Criteria: being on chronic hemodialysis for more than 3 months; presence of pruritus Exclusion criteria: any kind of allergic, dermatologic or hepatic disease which can be associated with pruritus. Statistical population: all the patients under hemodialysis in Imam Hospital Sample size: at least 6 patients Intervention: Increasing dialysis adequacy by increasing dialysis time or increasing the blood flow, or using dialysis membranes of high efficiency or higher flux Intervention period: 12 weeks Primary outcome: change in the severity of pruritus measured by Visual Analogue Scale

##### Recruitment status

**Recruitment complete**

##### Funding source

Nephrology Research Center of Tehran University of Medical Sciences

##### Expected recruitment start date

2011-12-31, 1390/10/10

##### Expected recruitment end date

2012-07-02, 1391/04/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201111027973N1**

Registration date: **2012-02-16, 1390/11/27**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-02-16, 1390/11/27

##### Registrant information

###### Name

Seyed Mansour Gatmiri

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6119 2679

###### Email address

##### Scientific title

Effect of Increased Dialysis Adequacy Measured by Kt/V index on Uremic Pruritus in Hemodialysis Patients of Imam Khomeini Hospital in 2012

##### Public title

Effect of More Adequate Dialysis on Itching in Dialysis Patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: being on hemodialysis for more than 3 months; presence of pruritus Exclusion criteria: Any kind of active allergic, dermatologic or hepatic disease to which the pruritus can be attributable.

##### Age

From **17 years** old to **80 years** old

##### Gender

Both

##### Phase

N/A

##### Groups that have been masked

No information

### Sample size

Target sample size: 30

### Randomization (investigator's opinion)

N/A

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Single

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Nephrology Research Center of Tehran University of Medical Sciences

##### Street address

Nephrology Research Center, Dialysis Ward, Imam Khomeini Hospital, End of Keshavarz Boulevard, Tehran, Iran

##### City

Tehran

##### Postal code

1419733141

##### Approval date

2010-09-23, 1389/07/01

##### Ethics committee reference number

90-03-14-13208-44796

## Health conditions studied

### 1

#### Description of health condition studied

Uremic pruritus

#### ICD-10 code

L29.8

#### ICD-10 code description

Other pruritus

## Primary outcomes

### 1

#### Description

Severity of Pruritus

#### Timepoint

at the end of the 12th week

#### Method of measurement

Using visual analogue scale and questionnaire

## Secondary outcomes

### 1

#### Description

patients' quality of sleep

#### Timepoint

at the end of the 12th week

#### Method of measurement

Using questionnaire

## Intervention groups

### 1

#### Description

Increasing Kt/V via increasing blood flow in access or using a higher efficiency membrane or using a higher flux membrane or increasing the time of dialysis.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital

##### Full name of responsible person

Seyed Mansoor Gatmiri

##### Street address

Dialysis Ward, Imam Khomeini Hospital, End of Keshavarz Boulevard, Tehran, Iran

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Nephrology Research Center of Tehran University of Medical Sciences

##### Full name of responsible person

Seyed Mansoor Gatmiri

##### Street address

Nephrology Research Center, Dialysis Ward, Imam Khomeini Hospital, End of Keshavarz Boulevard, Tehran, Iran

##### City

Tehran

##### Grant name

##### Grant code / Reference number

90-03-14-13208

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

Yes

##### Title of funding source

Nephrology Research Center of Tehran 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*

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## Person responsible for general inquiries

### Contact

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Nephrology Research Center of Tehran University of  
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**Full name of responsible person**  
Seyed Mansoor Gatmiri  
**Position**  
Nephrologist  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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Nephrology Research Center of Tehran University of  
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Azin Mohebi Nejad  
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General Practitioner  
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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*