# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Effects of three therapeutic methods (oatmeal (Avena Sativa) and diluted vinegar sponge bath and Routine Protocol) in reducing uremic pruritus in hemodialysis patients referred to the dialysis center of Birjand s' Valiasr hospital - (2013)

## Protocol summary


**Summary**

Objectives: The current study will be conducted to compare the effects of three methods (oatmeal (Avena Sativa), diluted vinegar sponge bath and Routine Protocol) on uremic pruritus. Avena Sativa lotion (Avena) is an anti-itch and a treatment product which has few complications but its effect on pruritus in patients with renal failure has not been well elucidated. Diluted vinegar is a safe, cheap and available liquid for all patients in comparison with highly complicated and expensive routine chemical treatment protocol. Design: This study is randomized cross-over clinical trial Setting and conduct: a) Participants: This study will be conducted in hemodialysis patients referred to the dialysis center of Birjand s' Valiasr hospital, the patients will be selected based on the study objectives via census method. Inclusion criteria consist of: at least 2 weeks history of Uremic pruritus; at least twice/ Tree times hemodialysis in week and Exclusion criteria : Severe side effects like an allergic reaction to the vinegar or oats b) Intervention: The subjects will be allocated to three groups randomly and after the wash out period each group will be treated with diluted vinegar, Avena Sativa lotion twice per day for two weeks, as well as routine protocol in this period after the wash out period, treatments will be changed in three groups cross overly. c) main outcome measures: Pruritus severity will be measured via a questionnaire and visual analog scale (VAS) that will be filled before and after each intervention.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2013021912525N1**

Registration date: **2013-03-16, 1391/12/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

**Registration date**

2013-03-16, 1391/12/26

**Registrant information**

**Name**

Samaneh Nakhaee

**Name of organization / entity**

Birjand Medical Sciences University

**Country**

Iran (Islamic Republic of)

**Phone**

+98 56 1444 3041

**Email address**

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**Recruitment status**

**Recruitment complete**

**Funding source**

Vice Chancellor for Research of Birjand Medical Sciences University

**Expected recruitment start date**

2013-03-10, 1391/12/20

**Expected recruitment end date**

2013-06-22, 1392/04/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effects of three therapeutic methods (oatmeal (Avena Sativa) and diluted vinegar sponge bath and Routine Protocol) in reducing uremic pruritus in hemodialysis patients referred to the dialysis center of Birjand s' Valiasr hospital - (2013)

**Public title**

The comparison of the effects of three therapeutic methods (oatmeal (Avena Sativa) , diluted vinegar sponge bath and Routine Protocol) in reducing uremic pruritus

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Patients must be referred to the dialysis center of Birjand Valiasr hospital: patients with renal failure (glomerular filtration rate less than60 ml/min for 3 months approved by a specialist): with at least twice/ Tree times hemodialysis in week: they must be experienced Uremic pruritus at least for 2 weeks: They must be don't have pruritus due to Dermal or non Dermal diseases. The absence of liver problems: Pregnancy and lactation: as well as acute inflammatory lesions of the skin: No known history of allergy were the other inclusion criteria. exclusion criteria: Unwillingness to continue participation in the study: Severe side effects like an allergic reaction to the vinegar or oats: Renal transplantation before end of therapy: Dyeing or emigration were identified as exclusion criteria.

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size:

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Crossover

**Other design features**

## Secondary Ids

**1**

**Registry name**

-

**Secondary trial Id**

-

**Registration date**

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**

Birjand Medical Sciences University ethics committee

**Street address**

Gafari street, Birjand University of Medical Science

**City**

Birjand

**Postal code**

**Approval date**

2013-02-17, 1391/11/29

**Ethics committee reference number**

14-11-1391

## Health conditions studied

**1**

**Description of health condition studied**

Chronic kidney disease

**ICD-10 code**

N18

**ICD-10 code description**

Chronic kidney disease

**2**

**Description of health condition studied**

pruritus

**ICD-10 code**

L29

**ICD-10 code description**

Pruritus

## Primary outcomes

**1**

**Description**

Uremic pruritus

**Timepoint**

Before and after each intervention and before dialysis

**Method of measurement**

Demographic checklist and pruritus questionnaire and Visual analog scale (VAS)

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

In the first group, patients will be treated by Avena lotion (made in Espanol company in Spain) twice per day for two weeks. After Wash out period the second treatment period will be continued by diluted vinegar6%(30 ml

vinegar/500ml water) twice per day for two weeks and after second Wash out period ,the subjects will receive routine protocol for two weeks.

**Category**

Treatment - Drugs

**2**

**Description**

In the second group, patients will be treated by diluted vinegar 6% (30 ml vinegar/500ml water) twice per day for two weeks. After Wash out period second treatment period will be continued by routine protocol for two weeks and after Wash out period, the subjects will receive Avena lotion (made in Espanol company in Spain) twice per day for two weeks.

**Category**

Treatment - Drugs

**3**

**Description**

In the third group, patients will be treated by routine protocol for two weeks. After Wash out period second treatment period will be continued by Avena lotion (made in Espanol company in Spain) twice per day for two weeks and after Wash out period ,the subjects will receive diluted vinegar 6%(30 ml vinegar/500ml water) twice per day for two weeks .

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Dialysis Ward in Valiasr hospital, Birjand

**Full name of responsible person**

Dr Jamile Morshedi

**Street address**

Gafari street, Valiasr hospital

**City**

Birjand

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Birjand Medical Sciences University, Vice Chancellor for Research

**Full name of responsible person**

Gholamreza Sharifzadeh

**Street address**

Gafari street, Birjand University of Medical Science

**City**

Birjand

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Birjand Medical Sciences University, Vice Chancellor for Research

**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*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Birjand Medical Sciences University

**Full name of responsible person**

Samaneh Nakhaee

**Position**

Master Student in Nursing

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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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*