

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

nakhaee67@bums.ac.ir

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 than 60 ml/min for 3 months approved by a specialist): with at least twice/ Three 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 vinegar 6% (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

Street address

Gafari street, Birjand University of Medical Science, School of Nursing and Midwifery

City

Birjand

Postal code

Phone

+98 56 1444 3041

Fax

Email

nakhaee67@bums.ac.ir;nakhaee38@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand Medical Sciences University

Full name of responsible person

Dr Ahmad Nasiri

Position

PHD in Nursing Faculty of Birjand Medical Sciences University

Other areas of specialty/work

Street address

Gafari street, Birjand University of Medical Science, School of Nursing and Midwifery

City

Birjand

Postal code

Phone

+98 56 1444 3041

Fax

+98 56 1444 0556

Email

nasiri2006@bums.ac.ir

Web page address

+98 56 1444 3041

Fax

Email

nakhaee67@bums.ac.ir;nakhaee38@yahoo.com

Web page address

Person responsible for updating data

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

Street address

Gafari street, Birjand University of Medical Science,
School of Nursing and Midwifery

City

Birjand

Postal code

Phone

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