

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of sertraline on uremic pruritis in hemodialysis patient

Protocol summary

Summary

Pruritus a common problem in dialysis patients, is sometimes precipitated or exacerbated by dialysis. Pruritus appearing only during treatment, especially if accompanied by other allergic symptoms, may be a manifestation of low grade hypersensitivity to dialyser or blood circuit components. More often than not, however, pruritus is simply present chronically and is noticed in the course of the treatment while the patient is forced to sit still for a prolonged period of time. Viral or drug induced hepatitis should be overlooked as a potential cause of such itching. Standard symptomatic treatment using antihistamines are useful. Ondansetron and naltrexone have failed to help in randomized trials. Acupuncture has helped chronically, general moisturizing and lubrication of skin using emollients recommended. Ultraviolet light therapy, especially UVB light, may be of help. Pruritus often is found in patient with elevated serum calcium product and or substantially elevated PTH level. Reduction in calcium, phosphate, and PTH are indicated. Whether uremic pruritus is helped by an increase dose of dialysis, use of high flux or polymethylacrylate membrane, capsaicin cream and activated charcoal, tacrolimus ointment or erythropoietin remain question for further investigations. Because uremic pruritus is common in 42-75 of hemodialysis patients and accompanied with sleep disorder, depression, disturbed quality of life and mortality, treatment is important. 50 patients chronically hemodialysed that dialysed 3 per week and have chronic pruritus more than 4 weeks selected. They should not use antihistamine, lubricant gabapentin. Randomly half of them take sertraline 50 mg 2 times per day and half take placebo. Pruritus evaluated in second, fourth, sixth and eighth week, scoring with DOU and VAS score done. In DOU evaluate severity, distribution and sleep disorder. In VAS we ask the patient that how much that feel pruritus and score from 1 to 10 and then sum DOU and VAS. In the beginning and end of study we check lab data: CBC, BUN, Cr, Na, K, AST, ALT, Ca, P, TG, CHOL, LDL, HDL, FBS, and PTH.

General information

Acronym

uremic pruritis (UP)

IRCT registration information

IRCT registration number: **IRCT2014080918736N1**

Registration date: **2014-09-05, 1393/06/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-09-05, 1393/06/14

Registrant information

Name

Noushin Hashemi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

vice chancellor for research shiraz university of medical science and researcher

Expected recruitment start date

2014-06-21, 1393/03/31

Expected recruitment end date

2015-04-20, 1394/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sertraline on uremic pruritis in hemodialysis patient

Public title

The effect of sertraline on uremic pruritis in hemodialysis patient

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: chronic pruritus more than 4 weeks that is resistant to other therapies; do not use lubricating in recent 2 weeks and gabapentin or antihistamines in recent 1 month; do not have hepatic failure. Excusion criteria: $Ca^{*p} > 55$; $PTH > 500$; $p > 5.5$; SLE patients that recieve cellcept or azathioprine.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

vice chancellor for research shiraz university of medical sciences

Street address

Zand street

City

Shiraz

Postal code

7193711351

Approval date

2014-06-22, 1393/04/01

Ethics committee reference number

38519

Health conditions studied

1

Description of health condition studied

Uremic pruritus

ICD-10 code

N18.9

ICD-10 code description

Chronic kidney disease, unspecified

Primary outcomes

1

Description

Pruritus

Timepoint

Every 2 for two months

Method of measurement

DOU and VAS score

Secondary outcomes

empty

Intervention groups

1

Description

take sertraline pill the patient recieve setraline 50mg 2 times per day and evaluate in second ans fourth and sixth and eighth week

Category

Treatment - Drugs

2

Description

take placebo the patient recieve pacebo like setraline 2 times per day and evaluate in second and fourth and sixth and eighth week

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebrahimi Dialysis center

Full name of responsible person

Mr Rasti

Street address

Sadra city

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor for research shiraz university of
medical sciences

Full name of responsible person

Dr. Seyed Basir Hashemi

Street address

Zand street

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

vice chancellor for research shiraz university of medical
sciences

Proportion provided by this source**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

2

Sponsor

Name of organization / entity

Researcher

Full name of responsible person

Noushin Hashemi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Researcher

Proportion provided by this source**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

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Position

Faculty member

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Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>