

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of high flux versus low flux on the quality of life in hemodialysis patients: a single blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect high flux versus low flux on the quality of life in hemodialysis patients. Design: a single blind randomized clinical trial. Setting and conduct: The eligible hemodialysis patients who will refer to Shahid Beheshti Hospital during the study period will be enrolled into the trial. Inclusion criteria: (a) age of 18 to 70 years; (b) a history of hemodialysis for at least 3 months. Exclusion criteria: (a) having acute cardiovascular or respiratory disease; (b) needing to transfusion; (c) having moderate or severe depression; (d) low level of conscious or agitation. Intervention group: Using high flux thrice a week for 12 weeks. Control group: Using low flux thrice a week for 6 weeks and then using low flux twice a week and high flux once a week for another 6 weeks. Primary outcome: Assessing the quality of life using quality of life questionnaire for hemodialysis patients (KDQOL-SF) before and 6 and 12 weeks after intervention. Secondary outcome: Assessing the life satisfaction using satisfaction with life scale (SWLS) before and 6 and 12 weeks after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506099014N68**

Registration date: **2015-06-17, 1394/03/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-17, 1394/03/27

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2014-07-29, 1393/05/07

Expected recruitment end date

2015-03-01, 1393/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of high flux versus low flux on the quality of life in hemodialysis patients: a single blind randomized clinical trial

Public title

Effect of high flux versus low flux on the quality of life in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) age of 18 to 70 years; (b) a history of hemodialysis for at least 3 months. Exclusion criteria: (a) having acute cardiovascular or respiratory disease; (b) needing to transfusion; (c) having moderate or severe

depression; (d) low level of conscious or agitation.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of flux used. Therefore, the trial will be run as single blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2015-02-23, 1393/12/04

Ethics committee reference number

D/P/16/35/9/6168

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

Z49.1

ICD-10 code description

Extracorporeal dialysis

Primary outcomes

1

Description

Assessing the quality of life

Timepoint

before and 6 and 12 weeks after intervention

Method of measurement

using quality of life questionnaire for hemodialysis patients (KDQOL-SF)

Secondary outcomes

1

Description

Assessing the life satisfaction

Timepoint

before and 6 and 12 weeks after intervention

Method of measurement

using satisfaction with life scale (SWLS)

Intervention groups

1

Description

Using high flux thrice a week for 12 weeks.

Category

Treatment - Devices

2

Description

Using low flux thrice a week for 6 weeks and then using low flux twice a week and high flux once a week for another 6 weeks

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Mehri Safari

Street address

Shahid Beheshti Hospital, Eram Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
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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

Vice-chancellor for Research the Technology, Hamadan
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

Person responsible for general inquiries

Contact**Name of organization / entity**

Shahid Beheshti Hospital

Full name of responsible person

Mehri Safari

Position

Nursing Student

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Person responsible for scientific inquiries

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Shahid Beheshti Hospital,

Full name of responsible person

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Position

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Person responsible for updating data

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Full name of responsible person

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Associate Professor

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Web page address

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