

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Clinical validation of Smart Flux hemodialysis filter made by Medica s.p.a company (Italy) with hollow fiber M-PES model, belongs to Mahan Med Meymeh Kish Company, in hemodialysis patients.

Protocol summary

Study aim

Evaluation the effect of smart flux filters on dialysis adequacy in hemodialysis patients and comparison of them with approved filters by the General Administration of Medical Equipment (GAME) used in hemodialysis centers Determination of BUN, URR and KT/V hemodialysis patients with smart flux filters Determination of BUN, URR and KT/V hemodialysis patients with other approved filters by the GAME Determination of possible complications such as itching - cramp - shortness of breath and hypotension in hemodialysis patients with smart flux filter Determination of possible complications such as itching - cramp - shortness of breath and hypotension in hemodialysis patients with other approved filters by GAME

Design

2x2 block randomization, non inferiority, parallel group open labeled clinical trial

Settings and conduct

All hemodialysis patients who refer to three hemodialysis centers in Isfahan from June 2019 for treatment of their disease and have the inclusion criteria to enter the study entered in to this non inferiority two parallel group crossover clinical trial.

Participants/Inclusion and exclusion criteria

1. Hemodialysis for more than 3 months 2. Age more than 20 and less than 75 3. Stable physical and laboratory state 4. Have hemodialysis 3 times a week. 5. Stable vascular access 6. Stable blood pressure status 7. Stable hemodynamic and cardiovascular state. 8. Free of acute infection or a malignancy. 9- Not severely anemic 10. Patients' written informed consent Exclusion criteria 1. Patient's consent withdrawal 2. Need for a blood transfusion 3. Need for hospitalization

Intervention groups

1. Hemodialysis with smart flux filter 2. Hemodialysis

with conventional filter

Main outcome variables

Evaluation of non inferiority of smart flux filters with those approved by GAME used in hemodialysis centers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090127001598N5**

Registration date: **2020-04-21, 1399/02/02**

Registration timing: **retrospective**

Last update: **2020-04-21, 1399/02/02**

Update count: **0**

Registration date

2020-04-21, 1399/02/02

Registrant information

Name

Shahram Taheri

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3625 5555

Email address

sh_taheri@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2020-02-19, 1398/11/30

Actual recruitment start date

2019-08-23, 1398/06/01

Actual recruitment end date

2020-03-05, 1398/12/15

Trial completion date

2020-03-05, 1398/12/15

Scientific title

Clinical validation of Smart Flux hemodialysis filter made by Medica s.p.a company (Italy) with hollow fiber M-PES model, belongs to Mahan Med Meymeh Kish Company, in hemodialysis patients.

Public title

Clinical validation of Smart Flux hemodialysis filter

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

To be on hemodialysis more than 3 months Age more than 20 year and less than 75 year. Have stable clinical and laboratory condition, (Corrected Ca>8mg%, K≤5.5 Hct>20%). Scheduled regular 3 times weekly hemodialysis program. Have stable vascular access. Have stable blood pressure. Have stable hemodynamic and cardiovascular condition, (for example no heart attack or cerebrovascular events in last three months). Have no acute infection or malignant tumors Have no severe anemia (hematocrit more than 20%) Patient give informed consent to participate in this clinical trial

Exclusion criteria:

Patient has uncontrolled high or low blood pressure (systolic BP less than 90 mmHg or more than 180 mmHg at the start of hemodialysis. For any reason the patient needs for blood transfusion. For any reason the patient needs hospitalization.

AgeFrom **20 years** old to **75 years** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **12**

Patients undergo hemodialysis 6 times with common filters and 6 times with Mahan Med Kish Company evaluating filters, in total 12 times

Actual sample size reached: **40**

More than 1 sample in each individual

Actual sample size in each individual: **12**

Patients undergo hemodialysis 6 times with common filters and 6 times with Mahan Med Kish Company evaluating filters, in total 12 times

Randomization (investigator's opinion)

Randomized

Randomization description

For this purpose, we will use the Quadratic Block Randomization method. For this purpose, we use the

numbered list of qualified people from the random number table in the computer system. People in Group I mean " Intervention "and C" are Comparison randomized. Eligible patients were randomly assigned to one of two intervention groups, the smart flux filter or routine filter filter control, based on the number I or C. After the random extraction of the numbers of a block, the above procedure is repeated for four patients. The dose will continue to reach the desired sample size.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

IR.MUI.RESEARCH

Street address

St. Alzahra Hospital, Soffeh Av.

City

Isfahan

Province

Isfahan

Postal code

817675731

Approval date

2019-09-29, 1398/07/07

Ethics committee reference number

1398.298

Health conditions studied**1****Description of health condition studied**

Hemodialysis adequacy

ICD-10 code

Z49.31

ICD-10 code description

Encounter for adequacy testing for hemodialysis

Primary outcomes**1****Description**

Hemodialysis adequacy

Timepoint

Before starting intervention and at the end of each phase

Method of measurement

laboratory measurement of BUN before and after the dialysis and calculating URR and KT/V.

Secondary outcomes

1

Description

Hypotension during and at the end of hemodialysis

Timepoint

At the start of each hemodialysis session and then every hour and at the completion of the hemodialysis session

Method of measurement

Measurement of systolic and diastolic blood pressure by sphygmomanometer

2

Description

Itching during hemodialysis

Timepoint

During each hemodialysis session

Method of measurement

Observe and record it by the responsible nurse

3

Description

clot formation in hemodialysis filter fibers during each hemodialysis session

Timepoint

During each hemodialysis session

Method of measurement

Observe and record it by the responsible nurse

4

Description

Shortness of breath

Timepoint

During each hemodialysis session

Method of measurement

Observed by the nurse in charge and measurement of blood oxygen saturation percentage by pulse oximeter

Intervention groups

1

Description

Intervention group: Hemodialysis filter with smart flux brand from Italy Medica s.p.a with halofiber model M-PES-1.5 low and high flux from Mahan Med Meymah Kish will be used for dialysis. Each patient in this group is hemodialysed with this type of filter for two weeks (6 sessions).

Category

Treatment - Devices

2

Description

Control group: In the comparison or control group, patients are hemodialyzed with approved filters (including meditechsys PS16 and 160 filters based on the type of filters studied using equivalent filters).

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Mojgan Mortazavi

Street address

Internal Dept., Al-Zahra Hospital, Soffeh Ave.

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3822 0000

Email

m_mortazavi@med.mui.ac.ir

2

Recruitment center

Name of recruitment center

Khorshid Hospital

Full name of responsible person

Shahrazad Shahidi

Street address

Hasht Behesht St., Ostandari's St.

City

Isfahan

Province

Isfahan

Postal code

8145831451

Phone

+98 31 3222 2127

Fax

+98 31 3222 2255

Email

atapour@med.mui.ac.ir

3

Recruitment center

Name of recruitment center

Abulfazl Charity Renal Therapy and Hemodialysis Center

Full name of responsible person

Shahram Taheri

Street address

Imam Khomeini street

City

Isfahan
Province
Isfahan
Postal code
8139914477
Phone
+98 31 3334 5554
Email
sh_taheri@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mahan Med Meymeh Kish
Full name of responsible person
Ali Karimi
Street address
No9. Kardan St., Noavarav Sq., Industrial Zone 3, Kish Island
City
Kish
Province
Hormozgan
Postal code
7941955349
Phone
+98 31 3221 8354
Email
info@mahanmed-mfg.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mahan Med Meymeh Kish

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shahram Taheri
Position
Associate Prof.
Latest degree
Subspecialist

Other areas of specialty/work

Nephrology

Street address

Internal Medicine Dept., Al-Zahra Hospital, Soffeh Ave.

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3822 0000

Fax

+98 31 3668 4510

Email

sh_taheri@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shahram Taheri
Position
Associate Prof.
Latest degree
Subspecialist
Other areas of specialty/work
Nephrology
Street address
Internal Medicine Dept., Al-Zahra Hospital, Soffeh Ave.
City
Isfahan
Province
Isfahan
Postal code
8174675731
Phone
+98 31 3822 0000
Email
sh_taheri@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shahram Taheri
Position
Associate Prof.
Latest degree
Subspecialist
Other areas of specialty/work
Nephrology
Street address
Internal Medicine Dept., Al-Zahra Hosp., Soffeh Ave.
City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3822 0000

Email

sh_taheri@med.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

It should be decided in our institutional ethics committee.

When the data will become available and for how long

It should be decided in our institutional ethics committee.

To whom data/document is available

It should be decided in our institutional ethics committee.

Under which criteria data/document could be used

It should be decided in our institutional ethics committee.

From where data/document is obtainable

It should be decided in our institutional ethics committee.

What processes are involved for a request to access data/document

It should be decided in our institutional ethics committee.

Comments