Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 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)

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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.
Age
From **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
Isfehan
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.
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2

Recruitment center
Name of recruitment center
Khorshid Hospital
Full name of responsible person
Shahrzad Shahidi
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Email
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3

Recruitment center
Name of recruitment center
Abulfazl Charity Renal Therapy and Hemodialysis Center
Full name of responsible person
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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
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Person responsible for updating data

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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