Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of Mocozift oral syrup (based on Trachyspermum ammi L) on reducing the failure of arteriovenous fistulas in the first 4 weeks after surgery in End Stage Renal Disease patients (ESRD).

Protocol summary

Study aim
Determination of the effect of Mocozift oral-herbal syrup (based on Trachyspermum Ammi L) on the failure rate of arteriovenous fistulas in the first 4 weeks after surgery in End-Stage Renal Disease patients (ESRD).

Design
Is a randomized, blinded, controlled clinical trial with a sample size of 160 patients in which randomized allocation is a Balanced block randomization.

Settings and conduct
The study will be performed in Hasheminejad Hospital and is a two-way blind. Patients, interveners and researchers are blinded in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. ESRD patients who have been diagnosed by a nephrologist as candidates for implantation of an arteriovenous fistula of the wrist (Cimino fistula). 2. Patients in whom Cimino fistula is performed for the first time. 3.Patients whose blood pressure range is more than 60/100 mm / Hg and less than 145/90 mm/Hg on the day of surgery. 4. Patients older than 18 years Exclusion criteria: 1.Blood pressure below 100/60 mm/hg 2. Absence of a suitable vessel (helical vein or arterial atherosclerosis) or artery diameter less than 2 and vein diameter less than 2.5 mm 3. Patients who have used anticoagulants. 4.Their vascular system is prepared for Cimino fistula VA and is not suitable for radio cephalic VA. 5. Paralysis or ulceration of the organ where the fistula is to be implanted.

Intervention groups
From 2 weeks before the fistula implantation procedure and up to 2 weeks after surgery, the intervention group received 15 CC of Mocozift oral syrup daily, 15 minutes after each meal in three divided doses, and the control group received 15 CC of placebo syrup 15 minutes after each meal.

Main outcome variables
Mocozift syrup, Premature failure, accelerated maturation

General information

Reason for update

Acronym
AVF=Arteriovenous Fistulas ESRD= End Stage Renal Disease

IRCT registration information
IRCT registration number: **IRCT20180712040446N4**
Registration date: **2022-04-25, 1401/02/05**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-25, 1401/02/05**
Update count: **0**

Registration date
2022-04-25, 1401/02/05

Registrant information

Name
Atefe Sharif

Name of organization / entity

Country
Iran (Islamic Republic of)

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atf.sharif@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-02, 1400/12/11

Expected recruitment end date
2022-10-22, 1401/07/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of Mocozift oral syrup (based on Trachyspermum ammi L) on reducing the failure of arteriovenous fistulas in the first 4 weeks after surgery in End Stage Renal Disease patients (ESRD).

Public title
The effect of Mocozift syrup on the success of arteriovenous fistulas
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
ESRD patients who have been diagnosed by a nephrologist as candidates for implantation of an arteriovenous fistula on the wrist (Cimino fistula). Patients whom Cimino fistula is performed for the first time. Patients who blood pressure range is more than 60/100 mm / Hg or less than 145/90 mm/Hg on the day of surgery. Patients older than 18 years
Exclusion criteria:
Blood pressure below 100/60 mm/Hg Absence of a suitable vessel (helical vein or arterial atherosclerosis) or artery diameter less than 2 and vein diameter less than 2.5 mm Patients who have used anticoagulants. Their vascular system is prepared for Cimino fistula VA and is not suitable for radio cephalic VA. Paralysis or ulceration of the organ where the fistula is to be implanted.
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
Balance Block Randomization. In this method, random division is done in the form of "blocks" with a predetermined size. For example, if the size of block is 6, the random division operation takes place until the third person is randomly placed in one group, after which the individuals are automatically assigned to another group until the block of 6 is completed. The advantages of this method include the following: It is easy to implement and balance in the number of groups is guaranteed.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, both participants, researchers, and data analyzers are blinded
Placebo
Used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.
City
tehran
Province
Tehran
Postal code
1449614535
Approval date
2022-02-09, 1400/11/20
Ethics committee reference number
IR.IUMS.FMD.REC.1400.634

Health conditions studied

1

Description of health condition studied
Increased success of arteriovenous fistulas of the wrist
ICD-10 code
N18. 6
ICD-10 code description
End Stage Renal Dieases

Primary outcomes

1

Description
Reduction of premature failure of arteriovenous fistulas of the wrist
Timepoint
6 weeks after surgery
Method of measurement
Observation and examination

2

Description
Accelerate the maturation of arteriovenous fistulas
Timepoint
2 weeks before and 2 weeks after surgery
Method of measurement
Observation and examination

Secondary outcomes

1

Description
Erythrocyte Sedimentation Rate
Timepoint
Before and after the intervention (weeks 0 and 6)
Method of measurement
Blood Test

2

Description
Blood Urea Nitrogen (BUN)
Timepoint
Before and after the intervention (weeks 0 and 6)
Method of measurement
Blood Test

3

Description
C Reactive Protein (CRP)
Timepoint
Before and after the intervention (weeks 0 and 6)
Method of measurement
Blood Test

4

Description
Creatinine (Cr)
Timepoint
Before and after the intervention (weeks 0 and 6)
Method of measurement
Blood Test

5

Description
White Blood Cell Count (WBC)
Timepoint
Before and after the intervention (weeks 0 and 6)
Method of measurement
Blood Test

6

Description
Blood Hemoglobin
Timepoint
Before and after the intervention (weeks 0 and 6)
Method of measurement
Blood Test

7

Description
Red Blood Cell Distribution Width (RDW)
Timepoint
Before and after the intervention (weeks 0 and 6)
Method of measurement
Blood Test

8

Description
Prothrombin Time (PT)
Timepoint
Before and after the intervention (weeks 0 and 6)
Method of measurement
Blood Test

9

Description
Partial Thromboplastin Time (PTT)
Timepoint
Before and after the intervention (weeks 0 and 6)
Method of measurement
Blood Test

10

Description
International Normalized Ratio (INR)
Timepoint
Before and after the intervention (weeks 0 and 6)
Method of measurement
Blood Test

11

Description
Ferritin
Timepoint
Before and after the intervention (weeks 0 and 6)
Method of measurement
Blood Test

Intervention groups

1

Description
Intervention group: The duration of treatment and follow-up for each patient will be a period of 6 weeks. From 2 weeks before the fistula implantation procedure and up to 2 weeks after surgery, the intervention group is given 15 CC of Mocozift oral syrup daily, 15 minutes after each meal in three divided doses. Mocozift oral syrup will be prepared without any label and drug information and only by entering a code from the pharmaceutical Company to the Blue Rain Seed. Mocozift oral syrup is licensed by the Ministry of Health and the Food and Drug Administration.

Category
Treatment - Drugs

2

Description
Control group: The control group will be given 15 CC placebo syrup 15 minutes after each meal in three divided doses. Placebo syrup will be prepared without any pharmaceutical label and information and only by entering a code from the pharmaceutical Company to the Blue Rain Seed.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hasheminejd Kidney Center
Full name of responsible person
Dr.Morteza Khavaninzadeh
Street address
Vali-nejad Str, Vanak Sq. Vali-e-asr Boul, Tehran, Iran
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1969714713
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Email
support@hkc.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Abbas Motulian
Street address
Iran University of Medical Sciences Shahid Hemmat Highway Tehran 14496-14535, IRAN
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1969714713
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Email
ivco@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohmmad Kamalinejad
Position
Researcher of natural compounds and medicinal plants
Latest degree
Bachelor
Other areas of specialty/work
Traditional Medicine
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Person responsible for scientific inquiries

Contact
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Position
Associate professor
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Specialist
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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
Dr. Atefe Sharif
Position
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Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
Hasheminejd Kidney Center, Vali-nejad Str., Vanak Sq. Vali-e-asr Boul, Tehran, Iran
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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available