Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of unripe grape juice in the treatment of proteinuria: A randomized placebo-controlled clinical trial

Protocol summary

Study aim

The effect of immature grape juice in the treatment of proteinuria in membranous nephropathy or focal and segmental primary glomerulosclerosis

Design

Clinical trial, randomization with Rand excel software, double-blind, Patients and interveners are unaware of the type of intervention performed for each group

Settings and conduct

Among patients with membranous nephropathy or primary focal and segmental glomerulosclerosis referred to Imam Reza Hospital of Tabriz University of Medical Sciences, 60 patients (30 patients in the intervention and 30 in the control group) were randomly selected and the cans containing unripe grape juice sachets and placebo were coded as A and B by a person other than the researcher. The intervention group will receive one sachet containing 6.3 grams of powder of the mentioned formulation before breakfast and the control group received 6.3 grams of placebo daily for 2 months

Participants/Inclusion and exclusion criteria

Inclusion criteria : Patients with membranous nephropathy or primary focal and segmental glomerulosclerosis Exclusion criterias : pregnancy; lactation; Patients with concomitant disease

Intervention groups

Among patients with membranous nephropathy or primary focal and segmental glomerulosclerosis referred to Imam Reza Hospital of Tabriz University of Medical Sciences, 60 patients are assigned to one of the two intervention and control groups (30 people in each group).

Main outcome variables

Proteinuria is one of the major problems of patients with membranous glomerulopathy, in which treatment with various drugs might lead to inadequate response and even a refractory situation. in case of successful results using this intervention, which also has long been utilized as a food and seasoning agent, a significant improvement of protienuria can achieved and the patient's need for drugs with deleterious side effects can be reduced.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211206053292N1**
Registration date: **2021-12-28, 1400/10/07**
Registration timing: **prospective**

Last update: **2021-12-28, 1400/10/07**
Update count: **0**

Registration date

2021-12-28, 1400/10/07

Registrant information

Name

Fariba Mahmoodpoor

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 9331

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mahmoodpoorfa@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-10, 1400/10/20

Expected recruitment end date

2022-06-10, 1401/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of unripe grape juice in the treatment of proteinuria: A randomized placebo-controlled clinical trial

Public title

The effect of unripe grape juice in the treatment of proteinuria: A randomized placebo-controlled clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Membrane nephropathy or primary focal and segmental glomerulosclerosis Willingness to collaborate in the study in patients Age range 64-18 years

Exclusion criteria:

kidney Transplantation pregnancy lactation Allergy or Asthma and other Allergies herbal drug consumption from three months ago addiction, Cigarettes, Alcohol and Shisha using professional sport diseases : chronic inflammatory disease (like Rheumatoid Arthritis), Major Depression, Schizophrenia, Severe liver disease, cirrhosis, malignancies, severe infectious disease

Age

From **18 years** old to **64 years** old

Gender

Both

Phase

0

Groups that have been masked

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

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization method that will be done using a random number table and even numbers will be considered for one group and odd numbers will be assigned to another group.

Blinding (investigator's opinion)

Double blinded

Blinding description

For blinding, at the beginning of the study, the set of cans containing unripe grape juice sachets and placebo is coded as A and B by someone other than the researcher

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

kidney research center,Emam reza Hospital, Golgasht street, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Approval date

2021-11-15, 1400/08/24

Ethics committee reference number

IR.TBZMED.REC.1400.781

Health conditions studied

1

Description of health condition studied

Membranous Nephropathy

ICD-10 code

N05.2

ICD-10 code description

Unspecified nephritic syndrome with focal and segmental glomerular lesions

Primary outcomes

1

Description

24-hour protein content of urine

Timepoint

Before the intervention and 8 weeks after the start of the intervention

Method of measurement

Calorimeteri

Secondary outcomes

1

Description

Serum albumin content

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Measurements in the laboratory with standard materials and devices by the calorimetri method

Intervention groups

1

Description
Intervention group: in addition to the usual drug treatment, a bag of unripe grape juice (containing 6.3 grams of unripe grape juice powder) will be prescribed daily before breakfast for 2 months.
Category
Treatment - Drugs

2

Description
Control group: This group will receive the usual drug treatment along with a placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital(Tabriz)
Full name of responsible person
Dr. Mohammadreza Ardalan
Street address
Emam Reza Hospital, Golgasht street, Tabriz
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ardalan34@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Parviz Shahabi
Street address
Golghasht street, Tabriz University of Medical Sciences
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parvizshahabi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
DR.Mohammadreza Ardalan
Position
professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

Informed Consent Form

No - There is not 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

Not applicable

Title and more details about the data/document

At the request of other researchers, the requested information will be provided to them

When the data will become available and for how long

Start high access immediately after publishing and printing study results

To whom data/document is available

Academic and industrial researchers

Under which criteria data/document could be used

Trust and do not change the results

From where data/document is obtainable

Dr. Mohammad Reza Arlan Preferably via email ardalan34@yahoo.com

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

Send a request by email stating the reason for requesting the information and where and for what purpose it will be used.

Comments