

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 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

##### Email address

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

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614756

##### Phone

+98 41 3336 9331

##### Email

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

Golgasht street, Tabriz University of Medical Sciences

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614756

##### Phone

+98 41 3335 7310

#### Email

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

##### Street address

Emamreza Hospital, Golgasht Street.Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

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##### Phone

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##### Email

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## Person responsible for scientific 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

##### Street address

Imam Reza Hospital, Golgasht St, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614756

**Phone**

+98 41 3336 9331

**Email**

ardalan34@yahoo.com

## Person responsible for updating data

**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

**Street address**

Emamreza Hospital, Golgasht St, Tabriz

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**Province**

East Azarbaijan

**Postal code**

5166614756

**Phone**

009833369331

**Email**

ardalan34@yahoo.com

## 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**