

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the efficacy of syrup of Palm kernel extract on stone size in patients with kidney stones

#### Protocol summary

##### Study aim

Investigating the effect of palm kernel on kidney stones passing

##### Design

A randomized, controlled, double-blind, placebo-controlled clinical trial

##### Settings and conduct

In this study, patients referred to Imam Reza Hospital Kermanshah Clinic between the ages of 18 and 60 of both sexes with kidney stones smaller than 8 mm and located in upper and middle calyces were studied for three months after obtaining consent. Patients are divided into case and control groups. In each group, 20 participants in the control group were given conventional kidney stone remedies, such as diuretic and potassium citrate, and the treated group received 10 cc syrup every 8 hours. Patients are monitored monthly by ultrasound, blood and urine examinations and evaluated on the basis of shrinkage or excretion. They follow.

##### Participants/Inclusion and exclusion criteria

Age over 18 years old. The ability to swallow and eat the syrup used in the design. Have the necessary co-operation in the design. There is no allergen to any herbal remedy. The size of stones must not be larger than 8mm. They must be in middle and/or upper calyx.

##### Intervention groups

The syrup prepared from date kernel will be prescribed to the intervention group and routine treatment such as diuretics and potassium citrate will be given to the controlled group.

##### Main outcome variables

Stone size, passing of kidney stones, serological tests (Bun, Cr) and clinical exam for investigation for any complication

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20170225032756N2**

Registration date: **2019-11-05, 1398/08/14**

Registration timing: **retrospective**

Last update: **2019-11-05, 1398/08/14**

Update count: **0**

#### Registration date

2019-11-05, 1398/08/14

#### Registrant information

##### Name

Marzieh Marami haji agha

##### Name of organization / entity

Kermanshah Medical University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3427 6480

##### Email address

yshokoohinia@kums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research of Kermanshsh Medical University

#### Expected recruitment start date

2018-04-21, 1397/02/01

#### Expected recruitment end date

2019-04-21, 1398/02/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation of the efficacy of syrup of Palm kernel extract

on stone size in patients with kidney stones

## Public title

Evaluation of the effect of Palm kernel on size of kidney stones

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age is over 18 years old. The patient signs the written consent and co-operates during the study. (In cases where the patient is illiterate, the consent form is read by the researcher and, if consent is given, to the patient.) stone size (less than 8 mm) number of stones between 1-5 location of stones in the kidneys in middle and/or upper calyx

### Exclusion criteria:

Pregnant patients and nursing mothers Patients who are compelled to take other medications that interfere with recent treatment Patients with clinical conditions who are at risk of serious health Patients with severe plant allergy

## Age

From **18 years** old to **60 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Participant
- Investigator
- Outcome assessor

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization has been done in intervention and control groups by blocking method. Using the Excel sheet, we generated 20 groups with the block size of 2 people in each. Finally, we used the "Random" command to calculate the probability for each group. By sorting the probability, we selected 40 people, each allocated to intervention or those who received routine care.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In this study, blind patients and researchers are kept. Each patient received a sealed envelop containing the relevant code for the type of intervention. Patients will be prescribed to receive whether palmicort syrup or routine treatment from the drugstore in the university clinic. Therefore, although, the nephrologist was not blind, the radiologist and other researchers from school of pharmacy were blind. In addition, as both groups received medication, they are not aware of whether they have received the routine care or new treatment.

## Placebo

Used

## Assignment

Parallel

## Other design features

Doubling Succession and Single Central

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

##### Street address

Building No 2, shahid beheshti Blv., Kermanshah University of Medical Sciences, Kermansshah, Iran

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6715847141

#### Approval date

2016-07-13, 1395/04/23

#### Ethics committee reference number

kums.rec.1395.271

## Health conditions studied

### 1

#### Description of health condition studied

kidney stone

#### ICD-10 code

N00-N99

#### ICD-10 code description

xlv

## Primary outcomes

### 1

#### Description

the size of kidney stones; size of kidney stones will be assessed by a radiologist using sonography.

#### Timepoint

every month after starting the treatment until 3 months

#### Method of measurement

sonography

### 2

#### Description

Expulsion of stone

#### Timepoint

once a month

#### Method of measurement

sonography

## Secondary outcomes

### 1

#### Description

Hypertension: in those without history of high blood pressure, recording a blood pressure > 140/90

#### Timepoint

once a week after the starting of treatment

#### Method of measurement

measurement in physician office

## Intervention groups

### 1

#### Description

Intervention group : three times a day, every 8 hours, two tablespoons per meal or 5 cc Contains 4 gr active ingredient. Such patients receive low salt, low fat and low animal protein diet.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: patients receive routing treatment for kidney stones by PI (nephrologist) including diuretics plus potasium citrate. Such patients receive low salt, low fat and low animal protein diet.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza Hospital

##### Full name of responsible person

Dr. Katayoon Etemadi

##### Street address

Imam Reza Hospital. Sorkheh ligeh Blv. Kermanshah

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6734667149

##### Phone

+98 83 3427 6489

##### Email

marami.ent93@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

#### Name of organization / entity

Kermanshah University of Medical Sciences

#### Full name of responsible person

Mrs Heydarian

#### Street address

Shahid Beheshti Blv; Medical Sciences of Kermanshah University; Kermanshah

#### City

Kermanshah

#### Province

Kermanshah

#### Postal code

6715847141

#### Phone

+98 83 3838 4185

#### Email

marami.ent93@gmail.com

#### Grant name

----

#### Grant code / Reference number

----

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

Yes

#### Title of funding source

Kermanshah 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

School of Pharmacy

##### Full name of responsible person

Marzieh Marami

##### Position

Researcher

##### Latest degree

Master

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

School of Pharmacy. parastar Blv. Taghbostan. Kermanshah

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6734667149

##### Phone

+98 83 3427 6480

**Fax**  
+98 83 3427 6493  
**Email**  
marami.ent93@gmail.com  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Imam Reza Hospital  
**Full name of responsible person**  
Dr Katayoon Etemadi  
**Position**  
Assistant  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Internal Medicine  
**Street address**  
Sorzhzeh lizheh Blv. kermanshah  
**City**  
kermanshah  
**Province**  
Kermanshah  
**Postal code**  
6715847141  
**Phone**  
+98 83 3427 6489  
**Fax**  
**Email**  
marami.ent93@gmail.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
School of pharmacy  
**Full name of responsible person**  
Marzieh marami  
**Position**

researcher  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
School of pharmacy. parastar Blv. taghbostan Blv.  
Kermanshah  
**City**  
Kermanshah  
**Province**  
Kermanshah  
**Postal code**  
6734667149  
**Phone**  
+98 83 3427 6480  
**Fax**  
+98 83 3427 6493  
**Email**  
marami.ent93@gmail.com  
**Web page address**

## 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

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

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