

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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
Sorzhieh 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