

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

In vitro Effects of Hydroalcoholic Extract of Peganum on the contraction of the human ureter undergoing nephrectomy in vitro

Protocol summary

Summary

The purpose of this study was to determine in vitro Effects of Hydroalcoholic Extract of Peganum on the contraction of the human ureter. This study is a clinical trial of phase 3, single-centered. 30 ureter removed from patients undergoing nephrectomy with inclusion criteria: removed ureter samples from total nephrectomy. Exclusion criteria: Uterine tissue involved with cancer cells; Tissue infection; abnormal dilatation of the urethra are divided into five groups of six. The control group receive normal saline, The second group receive a hydroalcoholic extract of peganum harmala 1 mg per ml, The third group receive a hydroalcoholic extract of peganum harmala 2 mg per ml, Fourth group receive hydroalcoholic extract of peganum harmala 4 mg per ml and a and fifth group receive pravastatin very low dosage. The ureter tissue was removed by nephrectomy with any reason and was placed in a UW solution at 0 ° C and immediately transferred to the lab. The ureter was separated from the size of one to two centimeters and placed in a bath of oxygen containing argon solution with temperature (37 ° C and pH = 4.7) and placed vertically between two hooks of stainless steel. The upper hook was connected to a isometric transducer by a thread and then connected to the physiograph. A weight weighing 1 gram on the opposite side of the transducer lever hangs to the tissue to make a primitive stretch. Then, by adding potassium chloride the tissue was contracted and after reaching the tissue to maximum contraction to examine the mechanism of the effect of extract, tissue With peganum harmala, Normal Saline and Prazosin extracts, the percentage of contraction force changes on paper was recorded and calculated. contraction of ureter determine the response to treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017102210222N17**

Registration date: **2017-10-31, 1396/08/09**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-10-31, 1396/08/09

Registrant information

Name

Zahra Keivani

Name of organization / entity

Shahrekord University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 1222 0016

Email address

keivani@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In vitro Effects of Hydroalcoholic Extract of Peganum on the contraction of the human ureter undergoing nephrectomy in vitro

Public title

In vitro Effects of Hydroalcoholic Extract of Peganum on the contraction of the human ureter :

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: removed ureter samples from total nephrectomy. Exclusion criteria: Uterine tissue involved with cancer cells; Tissue infection; abnormal dilatation of the urethra

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Kashani street, shahrekord university of medical sciences, shahrekord

City

Shahrekord

Postal code**Approval date**

2017-01-15, 1395/10/26

Ethics committee reference number

IR.SKUMS.REC.1395.233

Health conditions studied**1****Description of health condition studied**

contraction of the human ureter

ICD-10 code

N13.7

ICD-10 code description

Vesicoureteral-reflux-associated uropathy

Primary outcomes**1****Description**

Contraction of ureter

Timepoint

During intervention

Method of measurement

Checklist

Secondary outcomes

empty

Intervention groups**1****Description**

The control group receive normal saline.

Category

Treatment - Drugs

2**Description**

The second group receive a hydroalcoholic extract of peganum harmala 1 mg / ml.

Category

Treatment - Drugs

3**Description**

The third group receive a hydroalcoholic extract of peganum harmala 2 mg / ml.

Category

Treatment - Drugs

4**Description**

Fourth group: receive hydroalcoholic extract of peganum harmala 4 mg / ml and .

Category

Treatment - Drugs

5**Description**

Fifth group: receive pravastatinvery by low dosage

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital in Shahrekord

Full name of responsible person

Majid Shirani

Street address

Parastar street, Kashani Hospital of Shahrekord
University of Medical Sciences, shahrekord

City

shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Shahrekord University
of Medical Science

Full name of responsible person

Dr. Kamal Solati

Street address

Kashani street, shahrekord university of medical
sciences, shahrekord

City

Shahrekord

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Shahrekord University of
Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Majid Shirani

Position

Urology surgeon,Associate professor

Other areas of specialty/work

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Position

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Position

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Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty