Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Public title
In vitro Effects of Hydroalcholic 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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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