

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison effect of combined extracts of cinnamon , black pepper and Valerian with oral diclofenac on improvement of urinary tract pain in adults

Protocol summary

Study aim

Comparing effect of hydroalcoholic extract of combined plants of Cinnamon black pepper and Valerian with diclofenac Na in treatment of urinary tract pain

Design

In this non blinded randomized parallel clinical trial, 80 Patients are allocated randomly with simple sequential allocation in one of the two groups (herbal extract or diclofenac) and receive the intervention of that group.

Settings and conduct

Adult patients older than 18 years old with moderate to severe urinary tract pain referring to Shahid Mofateh clinic of Yasuj suffering from moderate to severe urinary tract pain allocated in one of two groups. The first group will received combined extract of 3 herbs provided in form of capsule prescribed from start of pain for 10 days after meal. In second group tab diclofenac sodium 50 mg is prescribed every 8 hour same as first group. Pain severity of patients (by Visual analogue scale (VAS) and patient records will be checked and recorded by questionnaire during treatment and two weeks after that. Also at beginning and two weeks later urine analysis and renal function tests checked in all patients and will be recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adult patients older than 18 years old with moderate to severe urinary tract pain, having informed consent form
Noncompliance criteria:
Developing any side effects during study, pregnant women, renal failure, dyspnea, ulcer and inflammation of urinary tract, active infection and those with a history of herbal or medicinal allergy

Intervention groups

In intervention group combined extract of 3 herbs provided in form of capsule prescribed from start of pain for 10 days with after meal. In second group tab diclofenac sodium 50 mg is prescribed every 8 hour

same as first group

Main outcome variables

Severity of pain according to Visual analogue scales (VAS) and patient records by questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20081011001323N26**

Registration date: **2020-12-04, 1399/09/14**

Registration timing: **prospective**

Last update: **2020-12-04, 1399/09/14**

Update count: **0**

Registration date

2020-12-04, 1399/09/14

Registrant information

Name

Sadrollah Mehrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3334 6070

Email address

dr.mehrabi@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison effect of combined extracts of cinnamon , black pepper and Valerian with oral diclofenac on improvement of urinary tract pain in adults

Public title
Effect of combined extracts of cinnamon , black pepper and Valerian on improvement of urinary tract pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age older than 18 year old complain from flank pain or urinary tract pain Having informed consent to enter study
Exclusion criteria:
 Uncontrolled coagulopathy Azotemia Pregnancy Presence of active urinary tract infection Allergy to medical or herbal drugs Suffering from cardiovascular or pulmonary disease Suffering from hepatic disease

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
patients are allocated randomly with simple sequential allocation in one of the two study groups (combined extract of three herbs or diclofenac) by help of sealed envelope and receive the intervention of the same group. The unit of randomization will be the referred patient. In every envelope, one of two codes (A=combined extract) or (B=diclofenac) will be taken. The sealed envelopes will be placed at the disposal of the expert. With the referral of each patient one of the envelopes will be randomly selected by the patients and will be introduced as a study group. The stratification approach is not used. Concealment will not take place in the study.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yasuj University of Medical Sciences

Street address

Yasuj University of Medical Sciences, Mottahari srteet, Yasuj, Iran

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591741414

Approval date

2020-11-29, 1399/09/09

Ethics committee reference number

IR.YUMS.REC.1399.161

Health conditions studied

1

Description of health condition studied

Urinary tract pain

ICD-10 code

R39

ICD-10 code description

Other and unspecified symptoms and signs involving the genitourinary system

Primary outcomes

1

Description

The severity of pain in urinary tract

Timepoint

During the study , two weeks and one month after starting treatment

Method of measurement

With Visual Analogue Scale (VAS)

Secondary outcomes

1

Description

Developing drug allergy and hypersensitivity

Timepoint

During and at the end of study

Method of measurement

Patients records and exam

2

Description

Developing renal complications

Timepoint

During and at the end of study

Method of measurement

Check of urine and renal function tests

Intervention groups

1

Description

Intervention group: The combination of cinnamon extract, black pepper and Valerian in equal proportions and in the form of capsules (Armaghan Salamat Zagros Yasuj Company) is prepared and prescribed at a dose of 500 mg every 8 hours after a meal with a glass of water for 10 days.

Category

Treatment - Drugs

2

Description

Control group: Tab diclofenac Na 50 mg every 8 hour is prescribed with a glass of water for two weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mofateh clinic of Yasuj

Full name of responsible person

Sadrolleh Mehrabi

Street address

Shahid Mofateh clinic, Montazeri Street, Yasuj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Ali Mousavizadeh

Street address

Deputy of research, Yasuj University of Medical Sciences,, Motahari St

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health.epid@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Sadrollah Mehrabi

Position

Professor, Chairman of Urology Department, Yasuj University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Sadrollah Mehrabi

Position

Professor, Chairman of Urology Department, Yasuj
University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available