Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of adding cinnamon to toltrodine in the treatment of urinary incontinence in women

Protocol summary

Study aim
Investigating the effect of adding cinnamon to toltrodine in the treatment of urinary incontinence in women

Design
The present study is a double-blind, randomized clinical trial with parallel groups (using block randomization), conducted on a total of 80 patients.

Settings and conduct
This study is a double-blind randomized clinical trial conducted on patients with urgency urinary incontinence who present to the outpatient clinic of Reza Ashtiani Hospital in Arak. Patients are assigned to two groups (A and B) using block randomization (blocks of four) through the Sealed Envelope software. The medications are prepared in identical, coded capsules by an independent individual, and both the patients and the outcome assessors are blinded to group allocation. Finally, the two groups are compared in terms of outcomes.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All women diagnosed with urge urinary disorder; provision of informed consent to participate in the study. Exclusion criteria: Presence of significant underlying conditions, including systemic diseases (hepatic disorders, renal disorders, diabetes), autoimmune diseases such as multiple sclerosis, neurological disorders, and pelvic floor disorders such as cystocele and rectocele; history of allergy to cinnamon or its derivatives.

Intervention groups
Intervention group: Participants in the intervention group will receive a 1-gram cinnamon capsule (Dr. Abidi Pharmaceutical Co.) once daily for 6 weeks. Placebo group: Participants in the placebo group will receive a starch-filled placebo capsule once daily for 6 weeks.

Main outcome variables
Daily urinary frequency, Number of daily urgency urinary incontinence episodes, Number of daily urinary urgency episodes, Number of nocturia episodes per night

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191104045328N48**
Registration date: **2025-12-17, 1404/09/26**
Registration timing: **registered_while_recruiting**

Last update: **2025-12-17, 1404/09/26**
Update count: **0**

Registration date
2025-12-17, 1404/09/26

Registrant information

Name
Amin Haji seyyed hoseini

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3366 7583

Email address
amin.medstu@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-12-11, 1404/09/20

Expected recruitment end date
2026-02-09, 1404/11/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the effect of adding cinnamon to toltrodine in the treatment of urinary incontinence in women

Public title
Effect of cinnamon on the improvement of urgency urinary incontinence
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All women with urgency urinary incontinence Having informed consent to participate in the study
Exclusion criteria:
Presence of systemic diseases such as chronic liver disorders, kidney disorders, and diabetes Presence of autoimmune diseases such as multiple sclerosis and neurological disorders Presence of cystocele and rectocele History of allergy to cinnamon and its derivatives
Age
From **18 years** old to **70 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
The participants will be assigned to two intervention and placebo groups based on the randomization sequence that will be generated in advance. This sequence is unpredictable and its arrangement is completely random. Block randomization method with 4 blocks will be used to allocate the samples. In this way, using the site www.sealedenvelope.com, blocks of 4 letters A and B are randomly generated based on the sample size. The order of placement of letters A and B in each block from the first block to the last block is considered as a randomization sequence. The production of these blocks and their random sequence is completely done by this site and the researcher does not know how they are sequenced.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, a capsule resembling the cinnamon capsule, made of starch and serving as a placebo, will be prepared and administered to the placebo group; therefore, the participants will not be aware of their group allocation. The medications will be prescribed by the attending physician, who is the principal supervisor. The designated assistant will collect the patients' outcomes based on their medical record number or their name and surname and will provide them to the attending physician, who will then code the data. Therefore, the data collector, who is the resident responsible for the project, will remain blinded to the group assignments.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Arak University of Medical Sciences
Street address
Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran
City
Arak
Province
Markazi
Postal code
3848176941
Approval date
2024-09-29, 1403/07/08
Ethics committee reference number
IR.ARAKMU.REC.1403.207

Health conditions studied

1

Description of health condition studied
Urgency Urinary Incontinence
ICD-10 code
N39.41
ICD-10 code description
Urge incontinence

Primary outcomes

1

Description
Daily urinary frequency
Timepoint
At baseline, 3 weeks, and 6 weeks after the intervention
Method of measurement
Asking the patient

2

Description
Number of daily urgency urinary incontinence episodes
Timepoint
At baseline, 3 weeks, and 6 weeks after the intervention

Method of measurement
Asking the patient

3

Description
Number of daily urinary urgency episodes
Timepoint
At baseline, 3 weeks, and 6 weeks after the intervention
Method of measurement
Asking the patient

4

Description
Number of nocturia episodes per night
Timepoint
At baseline, 3 weeks, and 6 weeks after the intervention
Method of measurement
Asking the patient

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, patients will receive a 1-gram cinnamon capsule (Dr. Abidi Company) daily for 6 weeks.
Category
Treatment - Drugs

2

Description
Control group: In the placebo group, patients will receive a starch-filled placebo capsule for 6 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Rezaei Ashtiani Hospital
Full name of responsible person
Dr. Maryam Shokrpour
Street address
Sina Rezaei Ashtiani Hospital, Basij Square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3417 3601
Email
Maryam_shokrpour@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Behzad Khansari Nejad
Street address
Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3383 8319
Email
behzad.khansarinejad@arakmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Dr. Maryam Shokrpour
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Sina Rezaei Ashtiani Hospital, Basij Square, Sardasht, Arak
City

Arak

Province
Markazi

Postal code
3848176941

Phone
+98 86 3417 3601

Email
Maryam_shokrpour@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Amir Almasi Hashian

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Epidemiology

Street address
Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

City
Arak

Province
Markazi

Postal code
3848176941

Phone
+98 86 3383 8319

Email
amiralmasi2007@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Dr. Rezvan Omidi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Sina Rezaei Ashtiani Hospital, Basij Square, Sardasht, Arak

City
Arak

Province
Markazi

Postal code
3848176941

Phone
+98 86 3417 3601

Fax

Email
drrezvanomoidi@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
After conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.

When the data will become available and for how long
Access will be from 2026/01/21 to 2029/01/21 for 3 years.

To whom data/document is available
University researchers

Under which criteria data/document could be used
Academic researchers or university professors or students who intend to use the data of this study, after obtaining permission from the relevant people mentioned, can use the information of this study in the field of metallurgical studies or other relevant review studies. In addition, if requested, they can use the information of this study for the prerequisites of their future studies and the existence of questions and ambiguities. Using the information of this study is subject to mentioning the names and logos of the responsible persons in this study.

From where data/document is obtainable
Academic researchers and university faculty members, after initiating contact via message or email with the relevant supervisor, may request permission to access and use the data from Dr. Maryam Shekarpour. Dr. Maryam Shekarpour: Phone: +98-918-363-4212 Email: Maryam_shokrpour@yahoo.com Address: Sina Rezaei Ashtiani Hospital, Basij Square, Sardasht, Arak, Iran

What processes are involved for a request to access data/document
Letter writing should be done with professors and universities.

Comments