Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Aug 2026

Comparison of the effectiveness of the three treatment methodes; transecutaneous nerve stimulation by constant parameters, transecutaneous nerve stimulation by variasble parameters and treatment by Solifenacin

Protocol summary

Study aim

Comparison of the effect of three transcutanese tibial transurethomyelation methods with constant parameters (cTTNS) and variable parameters (vTTNS) and sulfinazin (SOL) in the treatment of urinary incontinence in postmenopausal women over 50 years of age

Design

Three arm parallel group randomised trial without blinded postoperative care and outcome assessment

Settings and conduct

The population under study is postmenopausal women with administrative incontinence who are randomly selected into three groups from among the patients referred to the clinics of the Hamadan University of Medical Sciences who have entered the study.CTTNS group: Tibial nerve stimulation with frequency of 20 Hz and 200 µs duration. VTTNS group: Initial tibial tibial stimulation with initial frequency of 20 Hz and initial 200 microsecond duration, which dipped the frequency in the frequency from 20 Hz to 14 Hz, and the duration increased to 300 microseconds and returned to the first state within two seconds. SOL group: patients take 5 mg of sulfinazin for 6 weeks every day.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Postmenopausal women 2- Age over 50 years 3- Urine excretion at least 8 times a day, based on history or voiding diary 4- More than once, the episode was an urgency with or without discretion Exclusion criteria: Sensitivity to sulfenacin or its elements Urinary retention Neuropathy

Intervention groups

CTTNS group: Tibial nerve stimulation with frequency of 20 Hz and 200 µs duration VTTNS group: Initial tibial tibial stimulation with initial frequency of 20 Hz and initial 200 microsecond duration, which dipped the frequency in the frequency from 20 Hz to 14 Hz, and the duration increased to 300 microseconds and returned to the first state within two seconds SOL group: patients take 5 mg of sulfinazin.

Main outcome variables

- Severity of incontinence - Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190202042581N2**
Registration date: **2019-06-20, 1398/03/30**
Registration timing: **prospective**

Last update: **2019-06-20, 1398/03/30**
Update count: **0**

Registration date

2019-06-20, 1398/03/30

Registrant information

Name

Mohammad Reza Asadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3423 0949

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m.asadi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date
2021-07-23, 1400/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of the three treatment methodes; transecutaneous nerve stimulation by constant parameters, transecutaneous nerve stimulation by variasble parameters and treatment by Solifenacin

Public title
Comparison of the effectiveness of the three treatment methodes; transecutaneous nerve stimulation by constant parameters, transecutaneous nerve stimulation by variasble parameters and treatment by Solifenacin
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Postmenopausal women Age over 50 years Urine excretion at least 8 times a day, based on history or voiding diary ore than once, the episode was an urgency with or without discretion
Exclusion criteria:
Sensitivity to sulfenacin or its elements Urinary retention Gastric retention Neuropathy Uncontrolled narrow glaucoma angle
Age
From **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **16**
Randomization (investigator's opinion)
Randomized
Randomization description
Random block method will be used to allocate patients to treatment groups.Packed packs will be used to hide. So that we have 48 envelopes in the package with only one preset code on it and there are no symptoms of the type of treatment on it.So when the patient came to the clinic. The therapist will receive a code from the researcher stamped on one of the envelopes in the package.After opening the envelope by the therapist, the type of treatment will be determined and the treatment will be assigned to the patient.
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 Hamedan University of Medical Sciences
Street address
Research and Technology Vice-Chancellor, Hamedan University of Medical Sciences, Fahmideh Blvd
City
Hamedan
Province
Hamadan
Postal code
6517838736
Approval date
2019-06-15, 1398/03/25
Ethics committee reference number
IR.UMSHA.REC.1398.217

Health conditions studied

1

Description of health condition studied
Women's urgent incontinence
ICD-10 code
N39.41
ICD-10 code description
Urge incontinence

Primary outcomes

1

Description
Severity of incontinence
Timepoint
At the beginning of the study and 6 weeks after starting treatment
Method of measurement
OABS questionnaire

2

Description
Quality of life
Timepoint
At the beginning of the study and 6 weeks after starting treatment
Method of measurement
Quality of Life questionnaire

Secondary outcomes

1

Description
The frequency of urinary leakage
Timepoint
At the beginning of the study and 6 weeks after starting treatment
Method of measurement
Patient report

2

Description
Frequent feelings of urgency
Timepoint
At the beginning of the study and 6 weeks after starting treatment
Method of measurement
Patient report

Intervention groups

1

Description
Intervention group: CTTNS group: Tibial nerve stimulation with frequency of 20 Hz and 200 µs duration
Category
Rehabilitation

2

Description
Intervention group: VTTNS group: Initial tibial tibial stimulation with initial frequency of 20 Hz and initial 200 microsecond duration, which dipped the frequency in the frequency from 20 Hz to 14 Hz, and the duration increased to 300 microseconds and returned to the first state within two seconds
Category
Rehabilitation

3

Description
Intervention group: SOL group: patients take 5 mg of sulfinazin for 6 weeks every day.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rehabilitation clinic of mobasher
Full name of responsible person
Hojat Radinmehr
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Saeed Bashirian
Street address
Hamedan, In front of Mardom Park, Hamedan University of Medical Sciences, Research and Technology Vice-Chancellor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Hojat Radinmehr
Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Position

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Latest degree

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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

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable