

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

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

Protocol summary

Study aim

Comparison of the effect of three transcutaneous tibial neuromuscular stimulation 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 μ s 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 sulfinazin or its elements Urinary retention Neuropathy

Intervention groups

CTTNS group: Tibial nerve stimulation with frequency of 20 Hz and 200 μ s 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)

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+98 81 3423 0949

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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 methods; transecutaneous nerve stimulation by constant parameters, transecutaneous nerve stimulation by variables parameters and treatment by Solifenacin

Public title

Comparison of the effectiveness of the three treatment methods; transecutaneous nerve stimulation by constant parameters, transecutaneous nerve stimulation by variables 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 more 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

AgeFrom **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

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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 μ s 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

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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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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