Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation of the Efficacy and safety of Pulsed Electromagnetic Stimulation on the improvement of urinary symptoms in women with urge incontinence, stress incontinence and mixed (urge/stress) incontinence referred to a private urinary incontinence treatment clinic

Protocol summary

Summary

Lower urinary tract symptoms or LUTS is common between women especially in 40-60 years old. There are many therapeutic methods for LUTS and incontinence such as behavioral therapy and biofeedback, pharmacological therapy, electrical stimulation and surgery. There is a new method called pulsed electromagnetic stimulation which seems to be less invasive and while improving symptoms has a positive effect on the quality of life of the patients. This clinical trial will be done on 100 women with urinary incontinence. At least 21 years of age and having reading and writing skills for the participants is required. People with history of known psychological illness will be excluded from the study. The severity of urinary incontinence will be determined by the 4 questions in the standard questionnaire BFLUTS. After that patients will undergo two sessions a week for 6 weeks. Each session will consists of 2 phases for 20 minutes that each will be 10 minutes and there will be 5 minutes of interruption between these 2 phases. The device will be used as a chair (NOVAmag NT-60) and the patient will sit on the chair and blow to the patient. After treatment, patients will be asked about possible side. Also, the score of the BFLUTS questionnaire will be calculated again 3 and 6 months after the treatment. The efficacy of the treatment will be to reduce the number of pads used by patient to 1 or 0. Also, the number of pads used will be examined as a separate variable to determine the total amount of pads used by patient before and after treatment and their differences in general.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201710034582N7**
Registration date: **2017-11-13, 1396/08/22**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-11-13, 1396/08/22

Registrant information

Name
Ali Hamidi Madani

Name of organization / entity
Urology Research Center, Guilan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 13 1552 5259

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hamidimadani@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Urology Research Center, Guilan University of Medical Sciences

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the Efficacy and safety of Pulsed Electromagnetic Stimulation on the improvement of urinary symptoms in women with urge incontinence, stress incontinence and mixed (urge/stress) incontinence referred to a private urinary incontinence treatment clinic

Public title
The effect of pulsed electromagnetic stimulation on the improvement of urinary symptoms in women with urinary incontinence

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: At least 21 years of age; ability to read and write; having one of the types of stress; urge or mixed incontinence Exclusion Criteria: Overflow urinary incontinence; acute and severe pelvic infections; severe heart arrhythmia; known psychological disease history; neurological disorders such as stroke; parkinson; epilepsy and MS; current pregnancy; previous surgery for treatment of incontinence; history of pelvic or gynecologic surgery in last 3 weeks or next coming 8 weeks; pelvic organs prolapsed surgery; trauma of pelvis or perineum; neurogenic bladder; previous magnetic stimulation therapy; simultaneous use of alpha adrenergic agonist drugs (terazosin, tamsulosin, doxazosin), diuretics and or using any drugs that exacerbate incontinence; pelvic organs prolapsed (POP); doubt to the bladder fistula; urinary tract infection or hematuria; residual urine volume>200 milliliters

Age
From **21 years** old to **139 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Guilan University of Medical Sciences

Street address
Rasht, Gas Sq., West Shahid Beheshti Blvd., opposite of Sepah Bank

City
Rasht

Postal code

Approval date
2017-07-01, 1396/04/10

Ethics committee reference number
IR.GUMS.REC.1396.138

Health conditions studied

1

Description of health condition studied
Urinary incontinence

ICD-10 code
N39.4

ICD-10 code description
Other specified urinary incontinence

Primary outcomes

1

Description
Treatment of urinary incontinence

Timepoint
3 and 6 months after intervention

Method of measurement
Calculate the relevant questions in the BFLUTS standard questionnaire

2

Description
Reducing the number of used pads

Timepoint
3 and 6 months after intervention

Method of measurement
Calculate the relevant questions in the BFLUTS standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Pulse electromagnetic stimulation using a NOVAmag NT-60 device for 6 weeks, a weekly two sessions and each session for 20 minutes

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Ali Hamidi Madani's private clinic
Full name of responsible person
Dr. Ali Hamidi Madani
Street address
Physicians Building, opposite the Shahed school, after the passing bridge, Namaz Garden
City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urology Research Centre, Guilan University of Medical Sciences
Full name of responsible person
Head of Urology Research Centre, Dr. Siavsh Falahatkar
Street address
Urology Research Centre, Razi Hospital, Sardar Jangal Street
City
Rasht
Grant name
10506
Grant code / Reference number
32
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Urology Research Centre, Guilan University of Medical Sciences
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
Urology Research Center, Guilan University of Medical Sciences
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Position
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Person responsible for scientific inquiries

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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