

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

To compare the effects of neuromodulation (transcutaneous tibial nerve stimulation(TTNS)) with manometric biofeedback on physiological and clinical factors in female with functional constipation

Protocol summary

Study aim

To compare the effects of neuromodulation (transcutaneous tibial nerve stimulation(TTNS)) with manometric biofeedback on physiological and clinical factors in female with functional constipation

Design

This will be a clinical trial including two interventional groups. Thereafter, the results will be compared in the groups. Based on previous studies, the sample size will be 15 patients per group (total 30). Patients will randomly be allocated in either biofeedback or TTNS

Settings and conduct

This study will be performed at the Shariati Hospital's Digestive Disease Research Institute and patients will receive consent form when they will be screened and examined by a gastroenterologist if they meet the inclusion criteria.

Participants/Inclusion and exclusion criteria

Female with functional constipation aged between 25 – 60 years, Definition of constipation based on Rome III criteria, No history of previous large-bowel surgery or cancer, Pregnant patient exclude from study

Intervention groups

In this study patients with functional constipation are examined by colorectal specialist, then Para clinical tests including: anorectal manometry, BET and CTT study, are performed for them. Baseline evaluation include patient completion of the SF36 QOL and the Wexner questionnaire, food and stool diary for three weeks. Nutritional advices, proper defecation technique, diaphragmatic breathing technique, physical activity and massage are trained for three weeks also. After one month, based on inclusion criteria, they will randomly assign to biofeedback or TTNS group. Intervention in the biofeedback group will be given for 5 sessions once a week, and in the TTNS group, 12 sessions, three times a week

Main outcome variables

Wexner and SF36 QOL questionnaire Score; Physiological parameter based on Anorectal manometry; Time of balloon expulsion test

General information

Reason for update

our research was register in the old version of IRCT, therefore for updating the information, we prefer to do in the new version

Acronym

IRCT registration information

IRCT registration number: **IRCT20090301001722N18**

Registration date: **2018-04-22, 1397/02/02**

Registration timing: **prospective**

Last update: **2021-01-08, 1399/10/19**

Update count: **2**

Registration date

2018-04-22, 1397/02/02

Registrant information

Name

Samira Karimpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for education

Expected recruitment start date

2018-05-07, 1397/02/17
Expected recruitment end date
 2020-03-10, 1398/12/20
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 To compare the effects of neuromodulation (transcutaneous tibial nerve stimulation(TTNS)) with manometric biofeedback on physiological and clinical factors in female with functional constipation

Public title
 Effects of transcutaneous nerve stimulation with biofeedback on physiological and clinical factors in female with constipation

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Female with functional constipation aged between 25 – 55 years Definition of constipation based on Rome III criteria
Exclusion criteria:
 The patient withdrew cooperation Pregnant or wishing to become pregnant History of neurologic diseases such as multiple sclerosis, stroke, or spinal cord injury Metabolic disorder such as diabetes, hypothyroidism, hypercalcaemia History of Congenital anorectal malformations History of previous large-bowel surgery or cancer History of irritable bowel syndrome Take anticholinergic or other constipating medications Skin eruptions at the site of stimulation History of recent surgery to the lower limb Metal implant in the lower limb Abnormal rectal sensation Failure of Traditional treatment

Age
 From **25 years** old to **60 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **30**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Simple Randomization The name of each group is written on a separate paper and the patient randomly chooses the own intervention group

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 Rehabilitation Faculty of Tehran University of Medical Science

Street address

Piche shemiran, Enghelab Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

6511111489

Approval date

2017-08-30, 1396/06/08

Ethics committee reference number

IR.TUMS.FNM.REC.1396.3299

Health conditions studied

1

Description of health condition studied

Constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

anal canal resting pressure

Timepoint

before and after of intervention

Method of measurement

anorectal manometry

2

Description

rectoanal inhibitory reflex

Timepoint

before and after of intervention

Method of measurement

anorectal manometry

3

Description

urge volume
Timepoint
before and after of intervention
Method of measurement
anorectal manometry

4

Description
max tolerable volume
Timepoint
before and after of intervention
Method of measurement
anorectal manometry

5

Description
max rectal pressure during straining
Timepoint
before and after of intervention
Method of measurement
anorectal manometry

6

Description
balloon expulsion test
Timepoint
before and after of intervention
Method of measurement
stopwatch

7

Description
bowel movement
Timepoint
before and after of intervention
Method of measurement
wexner questionnaire

8

Description
total score of wexner questionnaire
Timepoint
before and after of intervention
Method of measurement
wexner questionnaire

9

Description
Scores of 8 scales (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional and mental health) and physical and mental component summary of SF36
Timepoint
Before and after of intervention
Method of measurement
SF36 questionnaire

10

Description
Score of total and 4 scales (physical discomfort, psychosocial discomfort, worries and discomfort and treatment satisfaction) of Patient Assessment Constipation Quality Of Life (PAC-QOL) questionnaire
Timepoint
Before and after of intervention
Method of measurement
PAC-QOL questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
biofeedback intervention: 5 sessions once a week
Category
Rehabilitation

2

Description
Transcutaneous Tibial Nerve Stimulation intervention : 12 sessions, three times a week
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
digestive disease Research Institute(DDRI)
Full name of responsible person
Fatemeh Majidirad
Street address
Shariati hospital, North kargar
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2

Recruitment center
Name of recruitment center
Physical Medicine and Rehabilitation department of Firoozgar Hospital
Full name of responsible person
Fatemeh Majidirad

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Amir Ali Sohrab Pour

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7th floor, main building, keshavarz Blvd.

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1417653761

Phone

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Fax**Email**

tums_edu@tums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Rehabilitation Faculty, Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Majidirad

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available