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Tibial nerve stimulation for overactive bladder

Submission date	Recruitment status	[_] Prospectively registered
09/01/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/01/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/07/2021	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
The overactive bladder affects 4 out of 10 people, causing a huge economic burden and severely affects daily life. This medical condition impairs the quality of life of people as it causes sudden urges to urinate and involuntary loss of urine. Medications are the most used treatment but they have several adverse effects. There is new technology named neuromodulation (stimulating nerve activity) that may have a better impact on overactive bladders with no medical risks and a longer lasting impact. One of this technique called Tibial Nerve Stimulation which uses punctures in the leg in certain points specified by Chinese acupuncture called Splen-6 or Sanyinjiao. This procedure is painless, fast and has success in 60.6% of people, lasting as long as 24 months, with minimum adverse effects. The aim of this study is to evaluate the effects of a short number of sessions of Tibial Nerve Stimulation in persons who are suffering of overactive bladder.

Who can participate?
Adults over 18 years and older who are suffering overactive bladder

What does the study involve?
Participants are assigned to one of three groups. Those in the first group receive a single session of PTNS. Those in the second group perceive six sessions of PTNS over a two week period. Those in the last group receive a single dummy PTNS. Participants are followed for six 6 months. Each participant is asked to keep diaries documenting how many times they experience overactive bladder symptoms to assess the impact of their condition.

What are the possible benefits and risks of participating?
Participant may benefit from having the treatment for free, a no charge medical consultation and from having 24 hour access by phone to a Doctor. The participants who have the treatment have the possibility to reduce their symptoms in at least 60%. The risks are minimal like small pain or bleeding in the point of puncture as the procedure is painless.

Where is the study run from?
Centro de Urología Avanzada CURA (Mexico)

When is the study starting and how long is it expected to run for?
Janaur y2015 to December 2019

Who is funding the study?
Litomovil del Norte SA de CV/ Centro de Urología Avanzada CURA (Mexico)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
PTNS2016SHORT

Study information

Scientific Title
Percutaneous Tibial Nerve Stimulation (PTNS) for patients with overactive bladder syndrome: effect of number of sessions and gender

Acronym
PTNS2016SHORT

Study objectives
The effect of Percutaneous Tibial Nerve Stimulation (PTNS) in overactive bladder (OAB) syndrome patients depends of the number of session and the gender of the participant.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of Litomovil del Norte/Urological Avaced Center, 30/11/2015, ref: PTNS2016SHORT-30/11/2015

Study design
Longitudinal random consecutive case controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Over active bladder syndrome

Interventions
Participants are recruiting in accordance the inclusion criteria and provide consent to participate in the protocol.

Data is collected about age, evolution time, voiding diary, OABq-SD questionnaire (Part A) using an Excel database, and values processed using the statistical software SPSS 10. Participants are then non-randomly allocated to groups based on experiment design and sample size. Participants are allocated to one of three groups. Participants with a severe impact on their quality of life are not included in placebo group. Participants are blinded to which group they are allocated to.

Group 1:
Participants receive a percutaneous tibial nerve stimulation (PTNS) session. The PTNS procedure consists of using a 34 gauge needle electrode inserted at a 60 degree angle, 3 to 4 cm deep 34 gauge needle electrode inserted at a 60 degree angle, 3 to 4 cm deep, in a point approximately 5 cm cephalad to the medial malleolus and slightly posterior to the tibia. The device used is a Neuromuscular Electrostimulator EMS+2, STAODYN, (Staodyn, Inc, Longmont). Data is collected before and 24 hours after (PTNS) 30 minutes single session and is also again collected one, three and six months after the session.

Group 2:
Participants receive six 30 minute sessions of PTNS over a two week period (three sessions each week). Data is collected before the PTNS session (3 per week) and is also collected one, three and six months after.

Group 3 (Placebo group):
Participants receive the one 30 minute session of the placebo PTNS. This consists of using a 34 gauge needle electrode inserted at a 60 degree angle, only 2mm deep, 34 gauge needle electrode inserted at a 60 degree angle, 3 to 4 cms deep, in a point approximately 5 cm cephalad to the medial malleolus and slightly posterior to the tibia. The device is turned on but the electrode is disconnected. Data is collected before and 24 hours after the session and again at one, three and 6 months later.

As of 09/10/2018:
Group 4. Effect of PTNS on plevic floor muscles (PFM) in OAB patients. 18 volunteers. 14 active and 4 placebo.

Intervention Type
Mixed

Primary outcome(s)
Bladder activity (nocturia, incontinence or urgency and frequency)is measured using the patient diaries for Group 1 and Placebo Group at baseline, 24 hours, one, three and six months and for Group 2 at baseline, one, three and six months.

Key secondary outcome(s))
1. Overactive bladder symptoms are measured using OABq-SF Questionnaire Part A for Group 1 and Placebo Group at baseline, 24 hours, one, three and six months and for Group 2 at baseline, one, three and six months.
2. Overactive bladder symptoms are measured using Perception of Bladder Condition (PPBC) Questionaire for Group 1 and Placebo Group at baseline, 24 hours, one, three and six months and for Group 2 at baseline, one, three and six months

Completion date
30/06/2020

Eligibility

Key inclusion criteria
1. Adults (female and male) suffering refractory OAB syndrome, 8 or more micturitions in 24 hours and questionnaire OAB-q SF score ≥ 20 points
2. No response to medication
3. Evolution time ≥ 6 months
4. Agree to participate and sign informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
75

Key exclusion criteria
1. Urinary tract infection
2. History of congenital urogenital disease, radiation, bladder cancer or litiasis
3. People who can not participate because of religious, cultural or mental reasons
4. People who can not participate because of do not sign informed consent or unwilling to participate in the protocol
5. Pregnancy
6. Age less than 18 years old
7. History of taking OAB medication for less than 2 weeks before to start PTNS

Date of first enrolment
01/01/2016

Date of final enrolment
30/06/2018

Locations

Countries of recruitment
Mexico

Study participating centre
Centro de Urología Avanzada CURA
Av. Agricultura Poniente 514, Colonia Centro.
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33000

Sponsor information

Organisation
Centro de Urología Avanzada CURA

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Lito Movil del Norte SA de CV

Funder Name
Centro de Urología Avanzada (CURA)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from:
Carlos Pérez-Martínez MD
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IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		09/05/2019	17/05/2019	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes