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Efficiency of transcutaneous electrical nerve stimulation in the treatment of central and peripheral disorders

Submission date
27/11/2024

Recruitment status
Recruiting

Registration date
02/12/2024

Overall study status
Ongoing

Last Edited
02/12/2024

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Transcutaneous electrical nerve stimulation (TENS) has long been used in the treatment of pain of any etiology. For a long time, studies were carried out in an attempt to find out the secret of the analgesic effect of this method. Experimental studies have proven that TENS has three levels of action: local, segmental, and suprasegmental. Local effect develops by improving microcirculation and releasing anti-inflammatory drugs, stimulating cell regeneration and suppressing peripheral sensitization. The segmental analgesic effect is due to an increase in afferentation along fast fibers, causing stimulation of the gelatinous substance, and inhibiting afferentation along nociceptive fibers. Due to its suprasegmental action, TENS has an analgesic and anti-anxiety effect due to the release of central endorphins. However, there is not enough clinical research studying the recovery effect of TENS. In addition, there is no specific data on algorithms for the use of TENS in the treatment of various pathologies of the peripheral and central nervous system.

Who can participate?
Patients over 25 years of age who had pain due to pathology of the central or peripheral nervous system for more than 3 months.

What does the study involve?
Patients will be examined in different nosological groups. Currently, studies are planned in the following groups:
- Tension headache
- Migraine
- Post-stroke headache
- Cervicalgia
- Thoracalgia
- Low back pain.
- Tunnel syndromes
- Meralgia paresthetica
Each group will be divided into 3 subgroups depending on the characteristics of the applied

current: High-frequency low-amplitude TENS subgroup, Low-frequency high-amplitude TENS subgroup and Low-frequency low-amplitude TENS subgroup (Sham TENS).

What are the possible benefits and risks of participating?
The possible benefits of participating include relief from pain, improved motor and sensory function, and an overall improvement in quality of life. There are no known risks associated with participating in this study.

Where is the study run from?
Peoples' Friendship University of Russia (RUDN University), Medical Stomatology Institute

When is the study starting and how long is it expected to run for?
January 2023 to July 2029

Who is funding the study?
RUDN University

Who is the main contact?
Prof Al-Zamil Mustafa, mustafaalzamil33@gmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

45453

Study information

Scientific Title
Analgesic and recovery effect of transcutaneous electrical nerve stimulation in treatment of central and peripheral neurological disorders

Acronym
TENS effect

Study objectives
To study the dynamics of pain, paresthesia, hypoesthesia and motor deficit after the use of transcutaneous electrical nerve stimulation in patients with pathology of the peripheral or central nervous system.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/04/2022, Local Medical Ethical Committee of Medical Dental Institute (Pskovskaya st. 7 - 1, Moscow, 127253, Russian Federation; +7 (499) 504-54-75; medinstmcu@inbox.ru), ref: 3111

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Medical and other records

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Pathology of the peripheral or central nervous system

Interventions
The treatment group receives effective transcutaneous electrical nerve stimulation. Each procedure lasts 20-30 minutes. The procedures are carried out 15 times every other day.
In the control group, sham transcutaneous electrical nerve stimulation is carried out with

electrical impulses of frequency 1 Hz, a duration - 50 μs, and an amplitude - mA.
The randomization process will be conducted by program software: Statistica Version: 12.0.1133.15 (x86/x64)

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Transcutaneous electrical nerve stimulation

Primary outcome measure
Before treatment, a week after treatment, after 2 months and 4 months of observation:
1. Pain assessment by visual analogue scale and Mc Gill Pain questionnaire
2. Assessment of impaired sensation: temperature, tactile and vibratory sensation by 5-point scale
3. Assessment of neurogenic claudication by Zurich Claudication Questionnaire (ZCQ)
4. Step activity monitoring by a pedometer
5. Motor deficit by 5-point scale
6. Electroneuromyography (ENMG):
6.1. Amplitude of Compound Muscle Action Potential (CMAP):
6.2. Terminal Latency
6.3. Conduction Velocity
6.4. Amplitude of Evoked Potential of Sural Nerves
6.5. F-wave and A-wave Abnormalities
7. MRI will measure the narrowing of the spinal canal at the L4-S1 level before and after decompression surgery and at the end of the follow-up period.

Secondary outcome measures
Before treatment, a week after treatment, after 2 months and 4 months of observation:
1. Quality of life by SF-36 questionnaire
2. Quality of enjoyment by Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q-SF)
3. Assessment of sexuality disorders by the Sexual Function Evaluation Questionnaire (SFEQ)

Overall study start date
04/01/2023

Completion date
01/07/2029

Eligibility

Key inclusion criteria

1. European
2. Adults aged from 25 to 60 years old
3. Neurological disorder is older than 3 months but less than 2 years
4. The severity of pain by visual analogue scale (VAS) is 5 scores and higher
5. Changes in the neurophysiological examination of the nervous system: electromyography, electroencephalography, evoked potentials
6. Signed voluntary informed consent to participate in this study

Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Lower age limit
25 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
300

Total final enrolment
115

Key exclusion criteria
1. Presence of allergic reactions to any of the drugs used
2. Severe cognitive disorders
3. Epilepsy
4. Rheumatoid diseases
5. Atherosclerotic peripheral arterial disease of the lower extremities
6. Muscular dystrophies of the lower extremities
7. Diabetes mellitus
8. Pregnancy
9. Undergoing physiotherapy or acupuncture treatment

Date of first enrolment
04/01/2023

Date of final enrolment
01/07/2029

Locations

Countries of recruitment

Russian Federation

Study participating centre
Medical Dental Institute
Pskovskaua 7-2
Mosvow
Russian Federation
127253

Study participating centre
RUDN university
Miklucho-maklaya 6
Moscow
Russian Federation
117198

Sponsor information

Organisation
Peoples' Friendship University of Russia

Sponsor details
6 Miklukho-Maklaya Street
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108851
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Sponsor type
University/education

Website
https://www.rudn.ru/

ROR
https://ror.org/02dn9h927

Funder(s)

Funder type
University/education

Funder Name
RUDN University

Alternative Name(s)
Российский университет дружбы народов, Rossiysky universitet druzhby narodov, Université RUDN, Universidad de Rusia de la Amistad de los Pueblos, , , Peoples' Friendship University of Russia

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Russian Federation

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository, RUDN Respiratory: https://repository.rudn.ru/ru/records/dissertations/. The type of data stored: Title of dissertations and scientific research.

IPD sharing plan summary
Stored in publicly available repository