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

**Submission date**
27/11/2024

**Recruitment status**
Recruiting

**Registration date**
02/12/2024

**Overall study status**
Ongoing

**Last Edited**
15/07/2026

**Condition category**
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## 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
- Peripheral and central sensory and motor deficit
- Cognitive disorders
- Cervicalgia
- Thoracalgia
- Low back pain
- Distal polyneuropathy

- Mononeuropathy
- Neurogenic erectile dysfunction
- 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


### Contact name
Prof Mustafa Al-Zamil

### ORCID ID
https://orcid.org/0000-0002-3643-982X

### Contact details
Peoples' Friendship University of Russia, Sherbinka, st. Rabochaya 2 - 42
Moscow-Sherbinka
Russian Federation
108851
+7 89262893810
alzamil@mail.ru


# Additional identifiers

### Protocol serial number
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

## Primary study design
Interventional

## Study design
Interventional randomized controlled trial

## Study type(s)
Prevention, Safety, Treatment, Other

## 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

## Phase
Not Applicable

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

## Primary outcome(s)

Current primary outcomes as of 06/05/2026:
Before treatment, a week after treatment, after 2 months and after 4 months of observation:
1. Pain assessment by visual analogue scale and McGill Pain Questionnaire
2. Assessment of impaired sensation: temperature, tactile and vibratory sensation by a 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.
8. Postural control examination and posturography

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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.

### Key secondary outcome(s)
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)

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
25 Years

### Upper age limit
60 Years

### Sex
All

### 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

**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

## 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

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 26/06/2026 | 15/07/2026 | Yes | No |