ISRCTN17718049 https://doi.org/10.1186/ISRCTN17718049

Exploring how gentle nerve stimulation in the ankle affects the body's automatic functions in healthy people

Submission date 19/12/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/12/2025	**Overall study status** Completed	
Last Edited 30/09/2026	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Public, Principal investigator, Scientific

Contact name
Dr Javier Muñoz

ORCID ID
https://orcid.org/0009-0002-7381-8797

Contact details
21 de mayo 145
Coyhaique
Chile
5950000
+56 991588386
doctormunozquintana@gmail.com

Additional identifiers

Study information

Scientific Title
Healthy volunteers receiving transcutaneous tibial nerve stimulation to assess acute changes in heart rate variability across baseline, stimulation and post-stimulation phases

Study objectives
Primary objective: To quantify acute changes in autonomic nervous system activity during and immediately after transcutaneous tibial nerve stimulation (TTNS) in healthy volunteers, using heart rate variability (HRV) metrics (e.g., RMSSD and SDNN) derived from standardized 5-minute segments.
Secondary objectives:
1. To compare sympathetic and parasympathetic indices and frequency-domain HRV measures (e.g., LF, HF, LF/HF) across baseline, stimulation, and post-stimulation phases
2. To assess the temporal pattern of autonomic modulation (during TTNS vs recovery) under a controlled supine resting protocol

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/10/2024, Comité Científico y Ético del Servicio de Salud Aysén (General Parra N° 551, Coyhaique, 5950000, Chile; +56 67 226 1400; arriagadapau@saludaysen.cl), ref: Ordinario N° 59-2024 (CEC)

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Basic science

Study type(s)

Health condition(s) or problem(s) studied
Acute autonomic nervous system modulation (heart rate variability, HRV) in healthy volunteers during transcutaneous tibial nerve stimulation (TTNS).

Interventions
Intervention: Transcutaneous tibial nerve stimulation (TTNS) delivered with a TENS device (TENS 7000®), continuous stimulation for 10 minutes at 30 Hz and 200 µs pulse width. Two self-adhesive surface electrodes were placed on the left foot/ankle (one at the heel and the other 3–5 cm above the medial malleolus). Correct positioning was initially confirmed by a brief motor response (toe flexion) at suprathreshold intensity, then stimulation was reduced and maintained below motor threshold at a comfortable sensory level.
Comparator: None (single-arm, within-subject baseline vs stimulation vs post-stimulation).

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Transcutaneous tibial nerve stimulation (TTNS) delivered using a TENS device (TENS 7000®).

Primary outcome(s)
1. Heart rate variability (RMSSD, ms) measured using Kubios HRV from R–R intervals recorded with a wearable heart rate monitor; analysed using a 5-minute segment at minutes 5–10 of each 10-minute phase: baseline, TTNS (stimulation), and post-TTNS (recovery).

2. Heart rate variability (SDNN, ms) measured using Kubios HRV from R–R intervals; analysed using a 5-minute segment at Minutes 5–10 of each 10-minute phase: baseline, TTNS (stimulation), and post-TTNS (recovery).

Key secondary outcome(s)

Completion date
30/12/2024

Eligibility

Key inclusion criteria
1. Adults (≥18 years)
2. Healthy volunteers without known chronic disease
3. Able to provide written informed consent
4. Comply with the study procedures

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. Recent surgery within 3 months
2. Current medications affecting autonomic function
3. Any condition preventing safe participation or valid HRV measurement

Date of first enrolment
11/12/2024

Date of final enrolment
30/12/2024

Locations

Countries of recruitment
Chile

Sponsor information

Organisation
Servicio de Salud Aysén

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/02/2026	30/09/2026	Yes	No
Basic results			21/01/2026	No	No