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The effects of dry needling on patients with muscle pain

Submission date
26/01/2025

Recruitment status
No longer recruiting

Registration date
28/01/2025

Overall study status
Completed

Last Edited
04/02/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Background and study aims
Dry needling (DN) is a therapeutic technique that involves inserting thin needles into specific points in muscle tissue, especially around myofascial trigger points (MTrPs), to relieve muscle pain and improve function. Studies have shown that DN can immediately improve biomechanical stiffness and muscle tone following treatment. While techniques involving DN can provide temporary relief, research suggests that factors such as manipulation and treatment dose significantly affect results. It has also been shown that different doses of DN can lead to different biochemical responses, indicating that the treatment effect may be dependent on the methods. The complex interaction between DN, biochemical markers, autonomic nervous system response, and pain modulation emphasizes the need for individualized treatment protocols. Ultimately, practitioners must consider both physiological effects and subjective patient experiences when using DN as a therapeutic intervention. Among the various methods used to relieve muscle pain with different DN methodologies, traditional dry-needling techniques stand out with the largest number of studies. However, there are still gaps in the literature on the methodology of static needling, i.e. leaving the needle for a specified time in the area of MTrPs, or conversely repeatedly irritating MTrPs via the Hong technique. Furthermore, there is a lack of information on the reactions associated with DN with physical medicine and manual therapy. Studies indicate that the Hong method may trigger some adverse reactions (transient pain, short-term inflammation), but adverse morphological changes do not occur. There is therefore an urgent need to verify the methodology of using DN due to the focused approach of treating trigger points in muscles in comparison with manual therapy and physical medicine. This project aims to assess the effect of DN and combined DN with manual therapy and physical medicine on the activity of the autonomic nervous system, pain modulation, muscle biomechanical properties, muscle strength, and myofascial tissue perfusion.

Who can participate?
Patients with myofascial pain syndromes and healthy volunteers aged 18 to 70 years

What does the study involve?
The study involves several protocols with participants randomly assigned to different groups. Project A: focuses on myofascial pain syndromes, dividing participants into four subgroups: experimental classic DN, experimental Hong DN, experimental static DN, and control (sham DN).

Measurements are taken at various intervals from before the intervention to 3 months after.
Project B: involves healthy volunteers without painful symptoms, also divided into the same four subgroups as Design A, with similar observation and measurement intervals.
Project C: targets myofascial pain syndromes again but includes subgroups for experimental classic DN, experimental laser therapy DN, experimental SWT DN, and control (sham). Measurements follow the same timeline as the other protocols.
Project D: targets myofascial pain syndromes, dividing participants into four subgroups for experimental classic DN, experimental intramuscular electrical stimulation, and control (sham). Various measurement devices are used to assess muscle and tissue properties, and all participants receive appropriate training in measurement and therapy techniques.

What are the possible benefits and risks of participating?
The project aims to assess the correlation between changes in capillary blood supply and muscle biomechanical properties after DN therapy and to assess the effectiveness of different methodological strategies of this therapy in treating muscle pain. The research results obtained within the proposed project should allow for understanding the connections between disturbed muscle tone and local ischemia in the area of MTrPs and determine which methodology is more beneficial for treating patients with myofascial pain in different body parts. DN therapy is minimally invasive, and a register of adverse events will be kept, which, in the light of research, may occur rarely and include subcutaneous hematoma, temporary nerve irritation manifested by slight numbness that disappears within 2 hours, fatigue, and drowsiness.

Where is the study run from?
The Proivita Medical Center in Żory (Poland)

When is the study starting and how long is it expected to run for?
November 2024 to December 2025

Who is funding the study?
The Jerzy Kukuczka Academy of Physical Education in Katowice, AWF Katowice (Poland)

Who is the main contact?
Dr Robert Trybulski, rtrybulski.provita@gmail.com

Contact information

Type(s)
Principal investigator

Contact name
Mr Robert Trybulski

ORCID ID
https://orcid.org/0000-0002-4276-4813

Contact details
al.Zjednoczonej Europy
37
Żory
Poland
44-240

+ 48 502591428
rtrybulski.provita@gmail.com

Type(s)
Public, Scientific

Contact name
Mrs Anna Lenzcewska

Contact details
al.Zjednoczonej Europy 37
Żory
Poland
44-240
696086912
provitazory@gmail.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Assessment of the effect of dry needling (DN) on changes in muscle biomechanical properties, pain threshold, autonomic nervous system, and transcutaneous perfusion in people with myofascial pain

Acronym
DN/TrPS/ANS

Study objectives
1. Hyperemic reactions depend on the type of DN therapy methodology
2. Changes in muscle strength and biomechanical properties of muscles depend on the type of methodology used
3. Reflex changes in the autonomic nervous system depend on the type of DN therapy methodology used
4. Combining DN therapy with manual therapy (ischemic pressure, rubbing, ice massage) is more beneficial for changes in hyperemia, pain modulation, muscle strength, biomechanical properties, tissue hyperemia and autonomic nervous system response
5. Combining DN therapy with physical medicine (Tecar therapy, focused shock wave, laser

therapy, inductive magnetic therapy) is more beneficial for changes in hyperemia, biomechanical properties of pain modulation, muscle strength and tissue hyperemia and autonomic nervous system response

Added 04/02/2025:
6. Intramuscular electrical stimulation (IMES) is more effective in treating myofascial pain than traditional dry needling and ischemic compression methods.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/01/2025, Committee on Ethics of Scientific Research of Physiotherapists Polish Physiotherapy Association (ul. Zygmunta Modzelewskiego 37, Warsaw, 02-679, Poland; +48 601 300 080; biuro@fizjoterapeuci.org), ref: -

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Diagnostic, Other, Treatment, Efficacy

Health condition(s) or problem(s) studied
Myofascial pain

Interventions
The study is based on several separate protocols, and participants were randomly assigned to several groups. Group assignment was achieved by simple 1:1 randomization using a random sequence generated on the randomizer.org website. The randomization process is independent of treatment duration and study personnel.

Design A (n=100) myofascial pain syndromes
The group will be randomly divided into subgroups:
experimental classic DN (eG=25)
experimental Hong DN (HG=25)
experimental static DN (eSG=25)
control, sham DN (cG=25).

Myofascial pain (TrPs) is localized to different body areas. The observation and measurement time is rest (before the study), during the intervention, immediately after the intervention, 1 hour 24 h, 48 h 7 days, 14 days, and 1, 2,3 months after the end of the intervention. The number of interventions is from 1 to 14.

Project B Healthy volunteers without painful symptoms
The group will be randomly divided into subgroups:
experimental classic DN (eG=25)

experimental Hong DN (HG=25)
experimental static DN (eSG =25)
control, sham DN (cG=25).

The observation and measurement time is rest (before the study), during the intervention, immediately after the intervention, 1 hour 24 h, 48 h 7 days, 14 days, and 1, 2, 3 months after the end of the intervention. The number of interventions ranges from 1 to 14.

Project C (n=100) myofascial pain syndromes
The group will be randomly divided into subgroups:
experimental classic DN (eG=25)
experimental Laser therapy DN (LG=25)
experimental SWT DN (eSwtG =25)
control, sham (cG=25).

Added 04/02/2025:
Project D (n=90) myofascial pain syndromes
The group will be randomly divided into subgroups:
experimental classic DN (eG=30)
experimental IMES (HG=30)
control, sham DN (cG=30).

Myofascial pain (TrPs) located in different areas of the body. The time of observation and measurement is rest (before the study), during the intervention, immediately after the intervention, 1 hour 24 h, 48 h 7 days and 14 days and 1, 2, 3 months after the end of the intervention. Number of interventions from 1 to 14.

Measurement devices: Myoton (Myoton AS, Myoton Ltd, Estonia 2021), inclinometer (Baseline USA 2020), body composition analyzer (Accuniq BC720, Korea), algometer (FPIX 5.2021 USA), Force Decks measuring platform (Vald Performance Australia), SONOMED DOPPLER MD4 (China 2020) with an 8 MHz head, Perimed Laser Flowmeter (Sweden 2004) with a 670 nm laser amplifier (near infrared). Used for 20 Hz sampling with a perfusion range of up to 10 V, the Sonoscape P20 ultrasound device with a 5-20 Hz linear head (China 2022). Electronic Pupilometers (Optopol Technology 2020 Poland) EMG device (Deymed TruScan 2022), and stabilometric platform with MPS pedobarograph (France, 2019),

Measurements are taken on the longissimus dorsi, sternocleidomastoid, quadriceps femoris, quadratus femoris biceps femoris, gastrocnemius, Achilles tendon, forearm extensors and flexors, rhomboids, levator scapulae, plantaris and at the top of the hallux (tips for LDF) at resting locations and positions. Applied in accordance with scientific literature and practical methods. Physiotherapists and students will receive appropriate training in measurement and therapy.

Intervention Type
Mixed

Primary outcome(s)
The following basic outcome parameters will be assessed at rest (before the intervention), during the intervention (real-time) immediately after the intervention, 1 h after the intervention, and after 24 and 48 h, 7, 14 days, and 1, 2, and 3 months:
1. Muscle tension (T [Hz]) measured using the Myoton device (Myoton AS, Myoton Ltd, Estonia 2021)

2. Flexibility (E [arb- relative arbitrary unit]) measured using the Myoton device (Myoton AS, Myoton Ltd, Estonia 2021)
3. Maximum isometric force (Fmax [kgf]) measured using an electronic dynamometer (Kinvent Froce, France 2021)
4. Reactive Strength Index (RSI [ms-1]) measured using the Force Decks measuring platform (Vald Performance, Australia)
5. Muscle pennation angle and thickness (PA- [%]) measured using an ultrasound device (Sonoscape P20, China 2022)
6. Transcutaneous electromyographic examination measured using an EMG device (Deymed TruScan, 2022)
7. Assessment of the center of gravity [cm2] measured using a stabilometry platform with a pedobarograph MPS (France, 2019)
8. Pupillometric assessment of pupil dilation response [mm2] measured using an electronic pupilometer (Optol Techniology, Polska 2020)
9. Heart rate variability (HRV) measurement (HRV) measured using HUAWEI WATCH D2 smartwatch (China, 2023)

Key secondary outcome(s))
The secondary outcome measures will be assessed at rest (before the intervention), during the intervention (real-time) immediately after the intervention, 1 h after the intervention, and after 24 and 48 h, 7, 14 days, and 1, 2, and 3 months:
1. Muscle bundle length measured using ultrasound imaging
2. Subjective level measured using the Borga scale questionnaire
3. Perfusion parameters (ABI brachial index, AOP occlusive pressure, TR, BZ, zero index and BZ /RF resting flowmeter) measured
using a perfusion monitoring device (e.g. Doppler laser flowmeter)
4. Level of serum catecholamines, creatine kinase and lactate measured using a blood sample test from an antecubital vein 10 ml max

Completion date
30/12/2025

Eligibility

Key inclusion criteria
1. Randomly selected healthy volunteers without active myofascial pain aged 18 to 70 years
2. Randomly selected volunteers aged 18-70 years with confirmed acute myofascial pain (latent and active myofascial trigger points - MTrPs) according to the MTrPs diagnostic criteria (Kietrys, D. M. et al. 2013, J. Sanchez et al. 2018)
3. Randomly selected volunteers with chronic myofascial pain (over 6 months)
4. Randomly selected volunteers with radicular pain due to C/TH and L/S discopathy

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Key exclusion criteria
Exclusion from the study will occur in the case of persons, treatment of injury:
1. Musculoskeletal injuries at the place of therapy not earlier than 3 months
2. Damage or unspecified skin lesions in the tissue area where measurements and therapeutic methods will be performed (DN and physical medicine).
3. Pregnant women
4. Fear of needles
5. Extreme fatigue
6. Haemophilia
7. Active infection
8. At the express request of the volunteer
9. Cancer patients
10. Epilepsy patients
11. Nickel allergy
Exclusion from the study may occur at any time during the experiment at the request of the participant.

Date of first enrolment
10/02/2025

Date of final enrolment
30/12/2025

Locations

Countries of recruitment
Poland

Portugal

Ukraine

Study participating centre
Cenrtum Medyczne Provita
al.Zjednoczonej Europy
37
Żory
Poland
44-240

Study participating centre
Physiotherapy Center Olaniszyn
Racibórz 47-400 ul. Zamkowa 4
Racibórz
Poland
47-400

Study participating centre
Lviv State University of Physical Culture
Kostiushka St., 11
79007 Lviv
Lviv
Ukraine
79007

Study participating centre
Instituto Politécnico de Viana do Castelo, Escola Superior de Desporto e Lazer
(Portugal) 4901-908 Viana do Castelo Avenida Capitão Gaspar de Castro
Viana do Castelo
Portugal
4901-908

Sponsor information

Organisation
Centrum Medyczne Provita

Funder(s)

Funder type
University/education

Funder Name
Akademia Wychowania Fizycznego im. Jerzego Kukuczki w Katowicach

Alternative Name(s)
The Jerzy Kukuczka Academy of Physical Education in Katowice, AWF Katowice

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Poland

Results and Publications

Individual participant data (IPD) sharing plan
Data sets collected during the research will be made available upon request and will be stored on the server of the Provita Medical Center - the research coordinator. The person responsible for storage and sharing is the project manager, Dr Robert Tryblski, email: rtrybulski.provita@gmail.com. The consent form that was attached to the application was signed by each participant, indicating their consent to share their data. The study was conducted in accordance with the Declaration of Helsinki with the approval of the ethics committee (consent attached to the application).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			27/01/2025	No	Yes
Participant information sheet			27/01/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes