Active Vibration Induced Treatment by Abdominal Excitation

Published: 10-07-2019
Last updated: 19-03-2025

1. To investigate the tolerability and safety of HALF-MIS used in elderly patients with chronic musculoskeletal pain.2. To investigate the effect on pain of HALF-MIS used in elderly patients with chronic musculoskeletal pain.3. To investigate the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue disorders NEC
Study type	Interventional

Summary

ID

NL-OMON49209

Source
ToetsingOnline

Brief title
ActiVitae

Condition

- Musculoskeletal and connective tissue disorders NEC

Synonym
musculoskeletal pain, rheumatism

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW

Intervention

Keyword: chronic musculoskeletal pain, non-invasive pain treatment, vibration therapy

Outcome measures

Primary outcome

per objective:

1. Safety and tolerability: (S)AE listings, UTAUT and ARTS

2. Self-reported pain: NRS

3. Quantitative Sensory Testing (QST)

Secondary outcome

per objective:

1. Not applicable

2. Pain disability index: PDI; Quality of life: EuroQoL 5D3L

3. Central sensitization index: CSI

Study description

Background summary

Chronic musculoskeletal pain is a disabling condition with huge individual and societal impact in Western society. A considerable amount of patients have decreased functional and biological capacities and lack resilience to stand current treatment standards, including surgery, or medication to handle their pain optimally. Besides, current treatments suffer from side effects. There is a high demand on the development of non-invasive treatments without side effects.

HALF-MIS (High Amplitude Low Frequency Music Impulse Stimulation)*, is an innovative treatment modality aimed at stimulation of the Pacinian bodies with

the use of infrasound to stimulate vagal activity. Previously, substantial effects were demonstrated on reduction of depression. It is, however, expected to be effective when used in pain management.

Study objective

1. To investigate the tolerability and safety of HALF-MIS used in elderly patients with chronic musculoskeletal pain.
2. To investigate the effect on pain of HALF-MIS used in elderly patients with chronic musculoskeletal pain.
3. To investigate the effect on central sensitization of HALF-MIS used in elderly patients with chronic musculoskeletal pain.

Study design

Placebo controlled pilot study

Intervention

Each patient will have a schedule consisting of 3 weekly treatments over the course of 3 weeks. Each session will last 20 minutes and 27 seconds according to the length of the music. In all of the eight visits, patients in the treatment group will undergo the HALF-MIS treatment.

Study burden and risks

In total there are 10 visits: 1 screening, 8 treatments and 1 follow-up. During the screening patients will be asked about their medical history and get a physical examination. During the first, last en follow-up visits patients have to fill in questionnaires. The first and last treatment visit, patients also undergo QST measurements. Previous trials in depression consistently reported positive effects of treatment and no lasting side effects. In some trials, symptoms such as dizziness and nausea are reported but they are always dose related and pass after the treatment session. Since patients get a pain treatment, the pain intensity might decrease during and/or after the treatments.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. The symptoms of pain have been present for 3 months or more
2. The symptoms of pain are present every day with a minimum level of NRS<=4 (Moderate and severe pain)
3. The symptoms of pain are resulting from a condition diagnosed as a musculoskeletal disease listed in the ICD-10 of the WHO M00-M99.9 (But NOT M50.0, M50.1, M51.0 and M51.1 that are Prolapsus Disci Intervertebralis with myelopathy/radiculopathies * as the pain syndrome in these cases are expected to be predominantly neurogenic)
4. Adequate communication and understanding of the language
5. Age * 65 years
6. Available during the intervention.

Exclusion criteria

1. The medical examination showing signs of significant active, untreated comorbidities. Excluded are patients with Delirium and/or psychotic symptoms or moderate or severe depression. The distinction between light depression and moderate and severe depression is done according to the ICD-10: Light depression is F32.0 * moderate and severe depression are F32.1 and F32.2.

2. Patients with decreased signs of autonomic responses, metal implants such as ICD, organ transplantations and surgery on central nervous system in history.
3. The medical examination showing signs of the pain syndrome being exclusively or predominantly neurogenic with the condition diagnosed as a neurological disease listed in the WHO G00-G99.8.
4. The belt doesn*t fit properly.
5. Pain related to malignancies.
6. Enrolled in any other clinical study within the duration of the current study.
7. Enrolled in other music therapy.
8. Incapable of giving consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-09-2019
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	RemPulse
Registration:	No

Ethics review

Approved WMO Date:	10-07-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-02-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 25538
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL69608.042.19
Other	NL7606
OMON	NL-OMON25538