The influence of musculoskeletal physiotherapy on the immune response in patients with neck pain.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON48587

Source
ToetsingOnline

Brief title
project MoTION

Condition

- Joint disorders
- Spinal cord and nerve root disorders

Synonym
chronic neck pain, non-specific persistent neck pain

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W,Nederlandse

Vereniging voor Manuele Therapie

Intervention

Keyword: Immune system, Neck pain, Physiotherapy

Outcome measures

Primary outcome

The main study parameters in subprotocol (1) are potential differences in cytokine concentrations between the three groups.

For subprotocol (2) the alteration in cytokine concentration from baseline to endpoint (immediately post-treatment and 120 minutes post-treatment) for the persistent non-specific neck pain group.

In subprotocol (3), the main parameter is the Global Perceived Effect (GPE) scale score.

Secondary outcome

The secondary outcomes for subprotocol 1,2, are: differences in self-reported questionnaires (neck disability index (NDI), International physical activity questionnaire (IPAQ), painDETECT (PD-Q), central sensitization inventory (CSI)) Visceral fat and Pain Pressure Threshold (PPT).

Additional for subprotocol (2) differences in serum cortisol (baseline and immediately post-treatment) will be added as a secondary outcome.

For subprotocol 1 and 2 phenotypic analysis of peripheral blood mononuclear cells will be compared.

Subprotocol (2) the Association between painscore and change in immune response after the Intervention.

Study description

Background summary

Neck pain is a major public health problem alleged in its high prevalence, substantial impact on daily life and huge societal costs. Musculoskeletal Physiotherapy (MP) is an effective treatment for patients with persistent non-specific neck pain and cervical radiculopathy for reducing pain intensity. The effects of MP are often immediately noticeable after treatment. However, it is currently unknown which working mechanism might cause these effects. In persistent neck pain patients, the immune response - cytokines concentration - identified through whole blood lipopolysaccharide stimulation is elevated compared to healthy control. MP is able to attenuate the in vitro immune response in healthy volunteers. Thereby, a potential mechanism of MP might be attenuation of the immune response. Therefore, the overall aim of this study is to gain insight into the immune response in patients with neck pain and cervical radiculopathy and the influence of MP on this immune response in neck pain patients

Study objective

The overall aim of this study is to gain insight into the pathophysiological mechanism of patients with non- specific neck pain and cervical radiculopathy and the influence of MP on these mechanisms. Therefore, different research objectives are formulated:
(1) To investigate whether the immune response is upregulated in persistent non-specific neck pain patients and patients with cervical radiculopathy compared to healthy controls.
(2) To investigate whether persistent non-specific neck pain patients treated with manipulative therapy show a different immune response directly after and 2h. after therapy compared to baseline and sham manipulation.
(3) To investigate whether the immune response at baseline is associated with recovery after four weeks in patients with persistent non-specific neck pain and cervical radiculopathy.

Study design

(1) Cross-sectional study; conducted in a primary care physical therapy practice.
(2) Randomised controlled trial; conducted in a primary care physical therapy practice. We will use blocked randomization to form an allocation list for the persistent non-specific neck pain patients who receive the placebo intervention (NP-C) and persistent non-specific neck pain patients who will receive the intervention (NP-MP). We will use a computer random number generator to select random blocks with a block size of 5 and 10 with an allocation ratio 1:4.

(3) Prospective cohort study with four weeks follow up; conducted in a primary care physical therapy practice.

Intervention

Patients with non-specific neck pain in subprotocol 2 who are allocated to the intervention group will receive a single high-velocity low-amplitude distraction manipulation at the cervico-thoracic region (C7-T4) and a low-velocity low-amplitude cervical mobilization at all of the restricted cervical segments (C0-C7). The placebo Intervention exist of position takening of the distraction manipulation but without the thrust.

Study burden and risks

The main burden of participating for subprotocol (1) will be collecting the blood samples (three for each group). For subprotocol (2) an additional of five blood samples will be taken, due to the circadian rhythm of cortisol, the time at which the blood collection occur is crucial to the final results. Therefore, the first blood collection will be performed between 08:00 and 10:00 A.M.

Another burden is that the venapuncties must be performed on an empty stomach which could give some discomfort. In total for all studies seven short and easy questionnaires need to be completed. Subjects in subprotocol (2) may experience side effects of the MP treatment during the first 24 hours e.g. headache, neck pain, dizziness, stiffness, muscle spasm, nausea, increase of current complaint and feeling low of energy. The benefits associated with the interventions in subprotocol (2) are a potential increase in cervical range of motion, and a decrease in pain intensity and physical complaint.

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

Persistent non-specific neck pain (research question (1)(2)(3))
Inclusion:
* Age between 18-65 years.
* Minimal score of 4 on the Numeric Pain Rating Scale.
* Persistent pain is defined as pain complaints longer than 6 weeks.
* Can be classified as grade 1 or 2 non-specific neck pain.
* By physical examination a range of motion deficiency on the cervico-thoracic junction and a cervical segment.
* Written informed consent of the subject.;Cervical radiculopathy (research question (1)(3))
Inclusion
* Age between 18-65 years.
* Minimal score of 4 on the Numeric Pain Rating Scale.
* Pain should be present for a minimal of six weeks.
* Cervical radiculopathy based on the clinical diagnosis confirmed by the Magnetic Resonance Imaging (MRI through a medical specialist). The compression must be caused by a discus protrusion or herniation.
* Written informed consent of the subject. ;Healthy control group (research question (1))
Inclusion
* Age between 18-65 years.
* Asymptomatic for neck or shoulder pain and other musculoskeletal conditions in the past 3 months.
* Written informed consent of the subject.

Exclusion criteria

Persistent non-specific neck pain (research question (1)(2)(3));A potential subject who meets any of the following criteria will be excluded from participation in this study:

* Pregnancy or postpartum for 9 months
* Contra-indications for phlebotomy (e.g. phlebitis)
* Underwent treatment for current complaints for the last 6 weeks (e.g. physiotherapy, manual therapy, GP etc.)
* Having mental health disorders (> 74 points on the MHI-5)
* Taken one of the following medication for the last 6 weeks: corticosteroids (e.g. prednisone), immunomodulatory medication (e.g. methotrexate, infliximab etc.) and the use of botox for the last 3 months.
* Taken one of the following medication: NSAID*s (e.g. diclofenac, ibuprofen, naproxen etc.), Aspirin, Simvastatin for the last two weeks.
* Jet lag (within 7 days), ongoing shift work and hippocampal damage.
* Having one of the following medical diseases
o Neurological disorders (e.g. MS, myelopathie, cervical stenosis etc.)
o Traumatic disorders (e.g. cervical fracture, surgery in the neck area etc.)
o Having a history of malignity
o Rheumatic or inflammatory disorders (e.g. Spondylitis Ankylpoetica, Crohn disease, sarcoidosis, colitis ulcerous, rheumatic arthritis, COPD, spastic colon, psoriasis etc.)
o Cardiac diseases (e.g. history of myocardial infarction, abnormal heart rhythms)
o Allergic reaction or auto immune diseases (e.g. type 1 diabetic, hay fever)
o Metabolic disorders (e.g. type 2 diabetic)
o Endocrinology disorders (e.g. Cushing Syndrome)
o Haematological disorders (e.g. clothing problem)
o Psychological/psychiatric disorders (e.g. depression, current high stress, , Alzheimer disease)
o Physical trauma for the last six weeks
o Having the flue;Cervical radiculopathy (research question (1)(3))
A potential subject who meets any of the following criteria will be excluded from participation in this study:
* Pregnancy or postpartum for 9 months
* Contra-indications for phlebotomy (e.g. phlebitis)
* Underwent treatment for current complaints for the last 6 weeks (e.g. physiotherapy, manual therapy, GP etc.)
* Having mental health disorders (> 74 points on the MHI-5)
* Taken one of the following medication for the last 6 weeks: corticosteroids (e.g. prednisone), immunomodulatory medication (e.g. methotrexate, infliximab etc.) and the use of botox for the last 3 months.
* Taken one of the following medication: NSAID*s (e.g. diclofenac, ibuprofen, naproxen etc.), Aspirin, Simvastatin for the last two weeks.
* Having one of the following medical diseases
o Neurological disorders (e.g. MS, myelopathie, cervical stenosis etc.)
o Traumatic disorders (e.g. cervical fracture, surgery in the neck area etc.)
o Having a history of malignity
o Rheumatic or inflammatory disorders (e.g. Spondylitis Ankylpoetica, Crohn disease, sarcoidosis, colitis ulcerous, rheumatic arthritis, COPD, spastic colon, psoriasis etc.)
o Cardiac diseases (e.g. history of myocardial infarction, abnormal heart rhythms)
o Allergic reaction or auto immune diseases (e.g. type 1 diabetic, hay fever)
o Metabolic disorders (e.g. type 2 diabetic)

o Endocrinology disorders (e.g. Cushing Syndrome)
o Haematological disorders (e.g. clothing problem)
o Psychological/psychiatric disorders (e.g. depression, current high stress, Alzheimer disease)
o Physical trauma for the last six weeks
o Having the flue;Control group (research question (1))
A potential subject who meets any of the following criteria will be excluded from participation in this study:
* Pregnancy or postpartum for 9 months
* Contra-indications for phlebotomy (e.g. phlebitis)
* Having mental health disorders (> 74 points on the MHI-5)
* Taken one of the following medication for the last 6 weeks: corticosteroids (e.g. prednisone), immunomodulatory medication (e.g. methotrexate, infliximab etc.) and the use of botox for the last 3 months.
* Taken one of the following medication: NSAID*s (e.g. diclofenac, ibuprofen, naproxen etc.), Aspirin, Simvastatin for the last two weeks.
* Having one of the following medical diseases
o Neurological disorders (e.g. MS, myelopathie, cervical stenosis etc.)
o Traumatic disorders (e.g. cervical fracture, surgery in the neck area etc.)
o Having a history of malignity
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o Haematological disorders (e.g. clothing problem)
o Psychological/psychiatric disorders (e.g. depression, current high stress, Alzheimer disease)
o Physical trauma for the last six weeks
o Having the flue

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-01-2019
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO

Date:	21-01-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC

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: 24888
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL61404.029.18