Different trajectories for people with acute neck pain: associations with biological, psychosocial and treatment-related factors.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29268

Source
NTR

Brief title
TAP

Health condition

Acute non-specific neck pain

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: 1) Vu University Amsterdam; 2) Dutch Association for Manual Therapy

Intervention

Outcome measures

Primary outcome

Latent trajectories whereby participants will be categorized based on their 2-, 4-, 6- weeks and 3-, 6- months NPRS and NDI score.

Secondary outcome

The participants will be checked for differences between trajectories in inflammatory markers, psychosocial factors, clinical characteristics and treatment related factors. Questionnaires will be filled in using paper questionnaires.

Inflammatory markers: Serum levels of high-sensitive CRP, TNF-α and salivary cortisol awakening response (CAR).
Psychosocial: catastrophising (PCS), anxiety, depression, stress (DASS21), sleep (PSQI), work, sports, physical activity (IPAQ), Illness perception (IPQ), kinesiophobia (Tampa).
Clinical characteristics: pain intensity (NPRS), disability (NDI), pain pressure threshold (PPT), wind-up, condition pain modulation (CPM), global perceived effect (GPE), range of motion (CROM).
Treatment related factors: Given treatment, number of treatments, medication use, used diagnostics (e.g. MRI, X-ray).

Study description

Background summary

Preventing persistence of non-specific neck pain will help to reduce the total burden of neck pain. Acute neck pain can be considered as a complex condition and several biological- and psychosocial factors interact bi-directionally and affect recovery. Currently, we are unable to predict who will recover and detailed information about the clinical course of people with acute neck pain is lacking. Recent insights show that the level of systemic inflammation and various psychosocial factors differ between recovered and non-recovered patients. Since the clinical course of people with acute neck pain is heterogeneous, it is important to identify different trajectories, and explore which biological-, psychosocial and treatment related factors are associated with recovery, and are different compared to non-recovery.

Study objective

We hypothesize that there will be different trajectories related to recovery in acute neck pain patients and that several biological, psychosocial and treatment related factors are associated with distinct trajectories. We hypothesize that the recovery trajectory will be associated with an early robust inflammatory response with intact cortisol awakening response (CAR). The non-recovery trajectory will be associated with ongoing inflammatory responses, a reduced CAR and more psychosocial discomfort compared to the recovery trajectory. In the current study we will use advances in biomedical and psychosocial assessment techniques to explore a range of characteristics from patients with acute neck pain. This exploratory study builds further on very recent developments within pain science

and can lead to a subsequent study with more participants.

Study design

All inflammatory markers, clinical characteristics and psychosocial assessments will be performed at baseline (T0), two weeks evaluation (T1), four weeks evaluation (T2), six weeks evaluation (T3), three months evaluation (T4) and six months evaluation (T5).

Intervention

Participants will not receive any treatment in the context of the present study. However, they are free to consume usual care conservative treatment such as physiotherapy or general practitioner care or self care. The number and modality of treatments will be recorded. We are interested in the different trajectories in the clinical course of people with neck pain. If the patients fits the inclusion/exclusion criteria the participant is eligible with or without treatment.

Contacts

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Eligibility criteria

Inclusion criteria

Non-specific neck pain patients will be eligible for participation if they are: 1) at least 18 years old, 2) within 2 weeks of onset of an acute neck pain episode, 3) lasting for >24h, 4) having sufficient knowledge of the Dutch language.

Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in this study:
• Pregnancy or postpartum for not more than 9 months or those who give breastfeeding;
• Contra-indications for venipuncture (e.g. phlebitis);
• Taking one of the following medications during the last 6 weeks: corticosteroids (e.g. prednisone), immunomodulatory medication (e.g. methotrexate, infliximab) and the use of botox for the last 3 months;
• Current participation in another clinical trial;
• Having a medical disease with immune system involvement (e.g. MS, Spondylitis Ankylpoetica).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	25-10-2020
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8892
Other	METC Brabant : Not yet received.

Study results