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

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1) Identify and describe different trajectories in the clinical course of people with acute neck pain. 2) Assess which biological-, psychosocial factors and treatments characteristics, differ between, and are most associated with the different...

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

Summary

ID

NL-OMON49410

Source
ToetsingOnline

Brief title
TAP: trajectories acute neck pain

Condition

- Joint disorders

Synonym
acute pain, Neck pain

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Immune system, Neck pain, Psychosocial, Recovery

Outcome measures

Primary outcome

Latent trajectories of the course of acute neck pain for pain intensity and disability.

Secondary outcome

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

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

1) Identify and describe different trajectories in the clinical course of people with acute neck pain.

2) Assess which biological-, psychosocial factors and treatments characteristics, differ between, and are most associated with the different trajectories.

Study design

Prospective longitudinal cohort study with 6-months follow-up.

Study burden and risks

The participants undergo in total 6 venipunctures of 5 ml each over a period of 6 months. Participants undergo physical tests, filling in questionnaires and venipunctures at baseline, week 2, week 4, week 6, month 3, and month 6. In total 30 ml whole blood will be taken. The process of venipuncture can be accompanied with small discomfort and small haemorrhage. All venipunctures will be performed by qualified personal with experience in blood taking. In the morning prior the venipunctures the salivary cortisol awakening response will be determined. Directly after awakening, 4 times salivary fluid will be extracted in a time period of one hour. Patients will be followed for a period of six months and it is allowed to receive treatment as usual during the time of the study.
Insight in different trajectories in the clinical course of acute neck pain and the complex interaction with biological-, psychosocial-, and treatment factors will lead to patient stratification and early insight into those who will recover poorly. Thanks to the acquired knowledge from this study, healthcare providers can be educated to deal with such complexity and increase recovery in the normally non-recovery group. This will reduce the burden of neck pain for the patient and society. To encounter the participant for any inconvenience 100 euro will be reimbursed after completion of the study. Travel and parking expenses will be reimbursed. The patients have a minimal of four days to consider if they want to participate in this study. By shortening the time to consider participation, it is possible to provide insight into different trajectories, even in the acute phase of acute pain.

Contacts

Public
Vrije Universiteit

Van der Boechorsstraat 9
Amsterdam 1081BT
NL
Scientific
Vrije Universiteit

Van der Boechorsstraat 9
Amsterdam 1081BT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

People with non-specific neck pain 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, and 4) having sufficient knowledge of the Dutch language.

Exclusion criteria

* Pregnancy or postpartum for not more than 9 months or those who give breastfeeding;
* Contra-indications for venipuncture;
* 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 invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2021
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	21-12-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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
CCMO	NL75140.028.20

Register	ID
Other	NL8892

Study results

Date completed: 06-06-2022

Actual enrolment: 50

Summary results
Trial is onging in other countries