The development of a prediction model for acute pain transitioning into pain persisting for more than 3 months after a visit to the emergency department

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We hypothesize (based on literature) that the incidence of chronic pain in The Netherlands is around 15-20% in patients presenting to the emergency department with (acute) pain related complaints. We have no further hypothesis, because of the...

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	Fractures
Study type	Observational non invasive

Summary

ID

NL-OMON22146

Source
Nationaal Trial Register

Brief title
PRACTICE

Condition

- Fractures

Health condition

Chronic pain Acute pain Emergency deparment Prediction model Factors of influence Predictors Netherlands Acute pijn Chronische pijn Spoedeisende Hulp Predictie model Voorspellend model Factoren van invloed Predictoren Nederland

Research involving
Human

Sponsors and support

Primary sponsor:	Stichting Coolsingel Research fund
Secondary sponsors:	Dutch Emergency Medicine Research fund (SGO-fonds)
Source(s) of monetary or material Support:	Stichting Coolsingel

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome
The primary objective is to develop and internally validate a prediction model for the transition to chronic pain (ongoing pain after 90 days) in patients with acute pain based on pre-defined predictors and patient characteristics.

Secondary outcome
To determine the cumulative incidence of chronic pain in all patients visiting the emergency department with acute pain.

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Study description

Background summary

Pain is one of the most common presenting complaints in an Emergency Department (ED). Nevertheless, undertreatment of this pain remains a problem. The consequence of undertreatment of patients with acute pain could be the transitioning into chronic pain. Chronic pain, defined as pain lasting for more than 3 months, is an important cause of healthcare (over)utilization. The incidence of chronic pain is still unknown, yet the prevalence is estimated to be 18% in The Netherlands. Until now, studies have focused on the treatment of acute pain on an emergency department and on identifying the risk factors for developing chronic pain. Differentiating patients at risk of developing chronic pain in an early stage can help prevent chronification as these patients can receive efficient and adapted treatment at an earlier stage. To our knowledge there were a few initiatives towards the development of a prediction model to distinguish patients in an early stage whom have an increased risk of developing chronic pain. However, those studies only determined the risk factors for the development of chronic pain in specific groups of patients.

Objective: To develop a prediction model to distinguish patients with an increased risk of developing chronic pain in an early – acute pain- stage and target them to efficient and adapted treatment to prevent the development of chronic pain.

Study design: Prospective multicenter longitudinal study

Study population: Patients 18 years and older who presented to the ED for a pain related cause and are not hospitalized.

During the first 7 consecutive days after visiting the ED, after 90 and 180 days patients will be asked to complete a short questionnaire using a specifically developed electronic application. The questionnaires will concern questions about general health, quality of life and pain. The first period of the trial, for the duration of 1 month, traditional paper questionnaires will be used to compare response rate between the web-based electronic survey and paper questionnaires.

Study objective

We hypothesize (based on literature) that the incidence of chronic pain in The Netherlands is around 15-20% in patients presenting to the emergency department with (acute) pain related complaints.

We have no further hypothesis, because of the observational aspect of our study. The list of candidate predictors for the development of chronic pain is based on a literature search in 2018.

Study design

1st August

Start period 1 (Start with paper questionnaires in Franciscus Gasthuis & Vlietland)

1st September

Continuation of period 1 (Start with electronical questionaires in Franciscus Gasthuis & Vlietland)

End of paper questionnaires

1st October

Stop with period 1

Start with period 2 (inclusion in all hospitals with electronic questionnaires)

January 2019 Introduction first article

February 2019 Methods first article

March 2019 Interim analysis & start syntax

April 2019

1st May 2019 END of inclusion period in all hospitals

June 2019 Statistical analysis

July 2019 Statistical analysis

August 2019 Finalize article

September 2019 Finalize article

October 2019 Finalize article

Intervention

No interventions

Contacts

Public
Sander Mol
[default]
The Netherlands
Scientific
Sander Mol
[default]
The Netherlands

Eligibility criteria

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

Inclusion criteria

* Age > 17 years, both sexes (adult patients).

* Acute Pain, existing < 48 hours as main complaint during ED visit

* Discharged after initial ED treatment

* Signed written informed consent

Exclusion criteria

* Cognitive impairment

* Illiteracy

* Language barrier

* Current diagnosis of chronic pain if located on or near the location of their current complaint

* Acute pain within 7 days after surgery

* Hospital admission

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2018
Enrollment:	1906
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	20-06-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL7079
NTR-old	NTR7277
Other	: 2018-39

Study results

Results posted: 17-08-2023

Actual enrolment: 1906

Summary results

"We included 1906 patients, of whom 825 participants completed 90 days of follow-up. Approximately 34.1% left the ED with an (V)NRS score ≥7, and 67.8% reported an (V)NRS score of ≥1 90 at days. Of all patients leaving the ED with an (V)NRS score ≥7, 76.5% developed chronic pain vs 63.2% of patients with (V)NRS score ,≥7 (P , 0.01). After correction, this difference was
borderline statistically significant with an odds ratio of 1.45 (95% confidence interval: 0.99–2.13, P 5 0.054). Various sensitivity analyses using a different (V)NRS at discharge and different definitions of chronic pain at 90 days showed a significant difference in the chronification of pain.

Conclusion: This study suggests that pain intensity at discharge from the ED, regardless of the localization or cause of pain,
increased the risk of developing chronic pain. By distinguishing patients at risk and providing an effective treatment, chronic pain
and the associated burden of disease might be preventable. "