Het ontwikkelen van een predictiemodel voor de transitie van acute pijn naar pijn die meer dan 3 maanden persisteert

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	Breuken
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22146

Bron
Nationaal Trial Register

Verkorte titel
PRACTICE

Aandoening

- Breuken

Aandoening

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

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor:	Stichting Coolsingel Research fund
Secundaire sponsoren:	Dutch Emergency Medicine Research fund (SGO-fonds)
Overige ondersteuning:	Stichting Coolsingel

Onderzoeksproduct en/of interventie

- Overige

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

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.

For this the 90 days cumulative incidence of chronic pain has to be observed.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

No interventions

Contactpersonen

Publiek

Sander Mol
[default]
The Netherlands

Wetenschappelijk

Sander Mol
[default]
The Netherlands

Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

* Volwassenen; Patiënten > 17 jaar,

* Acute pijn (pijn < 48 uur bestaand) als voornaamste klacht voor SEH bezoek

* Ontslag naar huis na behandeling op de SEH

* Gegeven informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

* Cognitieve beperkingen, analfabetisme en taalbarriére (niet kunnen begrijpen en of invullen

van vragenlijsten die nodig zijn voor het participeren in de studie)

* Indien ten tijden van SEH bezoek ook al chronische pijn op de locatie van de ingangsklacht

(N.B. chronische pijn op zichzelf is geen exclusie criterium)

* Acute pijn binnen 7 dagen na een chirurgische ingreep Acute

* Indien patiënt direct na het SEH bezoek wordt opgenomen in het ziekenhuis

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend
Doel:	Preventie

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-08-2018
Aantal proefpersonen:	1906
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	20-06-2018
Soort:	Eerste indiening
Toetsingscommissie:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7079
NTR-old	NTR7277
Ander register	: 2018-39

Resultaten

Datum resultaten gemeld:	17-08-2023
Totaal aantal deelnemers:	1906

Samenvatting resultaten
"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. "