The transition from acute to chronic pain in patients with acute musculoskeletal trauma

Published: 11-08-2011
Last updated: 29-04-2024

To determine the incidence of chronic pain and to identify risk factors for the development of chronic musculoskeletal pain after trauma to the extremities of the musculoskeletal system. Other objectives are determination of the prevalence of acute...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON38057

Source
ToetsingOnline

Brief title
PROTACT

Condition

- Other condition
- Fractures

Synonym
chronic pain, musculoskeletal trauma

Health condition

acute en chronische pijn

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: Schenking van Stichting Universiteitsfonds Twente voor onderzoek naar chronische pijn

Intervention

Keyword: acute pain, chronic pain, Musculoskeletal trauma, prognostic factors

Outcome measures

Primary outcome

Main study endpoint is the development of chronic musculoskeletal pain. Primary

outcomes are presence of pain (Yes/No) and pain severity (high/low intensity)

at 3, 6, and 12 months follow-up. Information about potential risk factors

(e.g. sociodemographics, pain -, injury and health characteristics) and health

care utilization of each patient will be collected.

Secondary outcome

not applicable

Study description

Background summary

Unrelieved chronic pain represents a major problem for individual patients and is also a socio-economic burden for health services and the community at large. Although the etiology of musculoskeletal chronic pain following trauma is not well understood, numerous retrospective studies have shown that a significant proportion (15%) of chronic pain patients have a history of traumatic injury. An unaddressed issue is the lack of knowledge to determine who will transit from an acute to a chronic pain state. Multiple determinants may be responsible for developing chronic pain. To understand more about this transition a follow-up study including patients with an acute pain onset over a prolonged period of time is needed. Early detection of risk factors and appropriate preventive strategies are necessary to avoid the development and subsequently

the consequences of chronic musculoskeletal pain.

Study objective

To determine the incidence of chronic pain and to identify risk factors for the development of chronic musculoskeletal pain after trauma to the extremities of the musculoskeletal system. Other objectives are determination of the prevalence of acute pain and epidemiological characteristics of patients with trauma to the extremities of the musculoskeletal system in the emergency department. Additionally, an inventory of health care utilization will be made for the cost analysis of acute and chronic musculoskeletal pain after trauma.

Study design

one year prospective follow-up study

Study burden and risks

Data from the hospital registration will be collected during their ED visit and subsequent visits relating to their injury and potential pain. Patients are asked to complete four or five questionnaires during a follow-up period of 12 months. The study is not an intervention study and no risks are expected related to this study. There are no direct benefits for the patients participating in this study. Primary objective is to determine risk factors for the development of chronic pain in acute musculoskeletal pain patients. The results of current study can lead to a solution to prevent the transition from acute to chronic pain and reduce the incidence of chronic pain in future patients

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

Adult patients with injury to extremities of the musculoskeletal system, who are admitted to the emergency department of Medisch Spectrum Twente, The Netherlands.
-injuries (fracture, soft tissue) due to a blunt trauma to the extremities of the musculoskeletal system
-Age: 18 years till 69 years
-Ability to read, speak and understand Dutch

Exclusion criteria

- Patients with a life or limb threatening condition (i.e. Manchester Triage categories one or two, defines as patient who needs immediate treatment and should be seen by a physician within 10 minutes, with an exception for patients with luxations, fractures coded with MTS II, who did not have other trauma. These patients will receive a invitation after medical treatment)
- Patients with polytrauma to the musculoskeletal system
- Patients with cognitive disability

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-09-2011
Enrollment:	2200
Type:	Actual

Ethics review

Approved WMO Date:	11-08-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	24-01-2012
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	31-05-2012
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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	NL36838.044.11