Pain management after conservative treatment of extremity fractures, a randomized clinical trial

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON39558

Source
ToetsingOnline

Brief title
Pain management after extremity fractures (conservative)

Condition

- Other condition
- Fractures

Synonym
broken bones, Pain after fractures

Health condition

pijn

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Stichting Merel

Intervention

Keyword: Conservative treatment, Extremity, Fractures, Pain

Outcome measures

Primary outcome

The main study parameters are the outcomes of the pain/satisfaction Numeric

Rating Scale.

Secondary outcome

The secondary study parameters are the outcomes of the self-efficacy scale and

the disability questionnaire.

Study description

Background summary

Fracture patients are prescribed a spectrum of analgesics to reduce pain. The conscious understanding of this pain may be altered by a variety of factors, including psychosocial factors. This could explain the apparent differences in prescription habits for analgesic drugs, between American and Dutch orthopaedic surgeons. There is currently no official (conservative) protocol for pain-management after extremity fractures. The large differences between the two countries emphasize how much there is to learn in this area of investigation.
In this project we will study the effects of two different frequently used analgesic regimens on pain relief, satisfaction with pain relief, and disability after skeletal trauma. This study will compare a step 1-(acetaminophen (paracetamol)) with a step 2-based (acetaminophen + tramadol) regimen. Current best evidence shows that it is highly possible that fracture patients nowadays receive more and stronger painkillers than needed. This study will be mandatory to provide a protocol for pain-management after extremity fractures.
In addition to drug management, it would be helpful to find predictors for pain

intensity and disability to aid the physician in clinical decision-making and assessing further management.

Study objective

The primary objective of this study is to determine (differences in) patient satisfaction with pain relief and pain intensity (Numeric Rating Scale) using a step 1 vs. a step 2 based analgesic regimen.
The secondary objective is to determine predictors of pain intensity and disability.
This will be mandatory to develop a useful protocol for pain-management.

Study design

This study is designed as a randomized clinical trial with short follow-up (2 weeks). Patients will be randomly assigned to either an acetaminophen based pain regimen, or a tramadol based regimen. We will measure self-efficacy in response to nociception and mood at enrollment. At time of follow-up (approx. 2 weeks) all patients will be given a questionnaire. They are asked to rate their overall worst and average pain, the level of pain that would be acceptable to them, overall satisfaction with pain relief (Numeric Rating Scale), and disability. In addition, we will use a database to record age, sex, trauma-site, fracture type, mechanism of injury, and comorbidity.
Intake will be *as needed* based, with a daily upper limit intake of: 1) acetaminophen (4x 1g) 2) tramadol (4x 50-100mg).

Study burden and risks

This study does not provide immediate advantage for the participating patient. For future patients however this study is beneficial, as it will evaluate the effectiveness of the current pain management after conservative treatment after extremity fractures. This study will likely reduce health costs. Participation in this study is of low risk, since the patients will not receive more medication then usual. It is not expected that patients will be undertreated, since each subject will receive a frequently used regimen. In addition, our previous prospective study showed adequate pain levels for patients who received step 1 (WHO pain ladder) medication.

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

All adult patients (age > 18) who will receive conservative treatment for an extremity fracture.

Exclusion criteria

Pregnant, breastfeeding or possibly pregnant patients and patients with relevant drug allergies will be excluded from study participation
Further exclusion criteria include: 1) phalangeal fractures; 2) stress fractures; 3) another fracture at any site; 4) pathological fractures; 5) inability to fill out questionnaires; 6) polytrauma patients with other significant injuries outside the skeletal system; 7) patients already receiving any chronic form of analgesic prior to injury; 8) liver or renal dysfunction; 9) diagnosed constipation; 10) patients receiving MAO-inhibitors.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Paracetamol
Generic name:	Paracetamol (acetaminophen)
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Tramal
Generic name:	Tramadol
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	14-05-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-05-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO Date:	10-12-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2012-001030-34-NL
CCMO	NL40004.018.12