High Loading Dose of Paracetamol in the Emergency Department

Published: 19-10-2020
Last updated: 09-04-2024

To investigate if a high loading dose of 2 grams paracetamol has a beneficial effect on pain sensation or has an opioid-sparing effect in patients with pain in the Emergency Department

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49837

Source
ToetsingOnline

Brief title
HiDoP

Condition

- Other condition

Synonym
pain

Health condition

patienten met pijn op de spoedeisende hulp

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Emergence Department, loading-dose, paracetamol

Outcome measures

Primary outcome

- Change in NRS-score.

Secondary outcome

Difference in the need for use of other analgetics. (NSAIDS, Opioids, Ketanest)

To examine if there is a change in the amount of side-effects during admission

in the Emergency Department after a high loading dose of Paracetamol has been

given.

Study description

Background summary

An adequate and quick analgesic effect is desirable in the Emergency Department where some patients can be in severe pain. There appears to be an absent ceiling effect of paracetamol. Also, a high loading dose of 2 grams can be given safely to healthy adults. Opioids have numerous undesirable side-effects like respiratory depression and vomiting, resulting in adverse events such as apnoea or aspiration.

Study objective

To investigate if a high loading dose of 2 grams paracetamol has a beneficial effect on pain sensation or has an opioid-sparing effect in patients with pain in the Emergency Department

Study design

a prospective double-blind placebo-controlled study.

Intervention

2 grams of Paracetamol given orally vs 1 gram of paracetamol given orally

Study burden and risks

The risks are negligible.

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

Age 18 years and older
Presence of acute pain (pain started less than 24 hours ago) with an NRS-score of >3

Exclusion criteria

- Weight <50kg
- Use of paracetamol in the last 6 hours
- Daily use of paracetamol
- Known pregnancy
- History of liver insufficiency and/or cirrhosis
- Kidney-insufficiency
- Malnutrition
- Alcohol-addicts
- Thoracic pain
- Patients suspect of intracranial hemorrhage
- Patients suspect of pain due to aneurysma or arterial dissection,
- Patients with chronic pain
- Impossibility to use NRS (physical or cognitive impairment)
- Non-Dutch speaking
- No informed consent
- Known allergy to paracetamol

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	198
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	acetaminophen
Generic name:	acetaminophen
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	19-10-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	EUCTR2018-002883-23-NL
CCMO	NL67739.042.19