Paracetamol and its Influence on the Opioid Requirement in Sufficient Pain Management in the ED

No registrations found.

Ethical review Positive opinion

Status Pending

Health condition type -

Study type Observational non invasive

Summary

ID

NL-OMON22636

Source

NTR

Health condition

Opioid use, pain

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Amsterdam

Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

The main study endpoint is the opioid requirement in Morphine Equivalent Units (MEU) between individual subjects who received additional paracetamol and those who did not.

Secondary outcome

Secondary outcome is the NRS measured an hour after administration of the opioid and at

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discharge, between individual subjects who received additional paracetamol at the ED and those who did not.

Study description

Background summary

Rationale:

In 2013 about 1.8 million patients visited an ED in the Netherlands, of whom approximately 30.000 attended the AMC. About 50-79% of all patients in the ED complained about pain, and in approximately 40% of these patients, pain was not treated properly.

Of all therapeutically used drugs, opioid analgesics are most frequently associated with adverse drug events. Combining drugs with different mechanisms of action may have an additive or synergistic effect and may lead to a reduction in adverse events. Adjacent paracetamol showed a decrease of approximately 20 to 25% in opioid requirements, postoperatively.

Study objective

The use of paracetamol reduces total opioid requirement in the ED and during the first 24 hours.

Study design

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Intervention

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Contacts

Public

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- patients 18 years or older presenting to the ED in the AMC
- an NRS of 4 or higher during presentation
- patients having received an opioid prehospitally (usually in the ambulance) or in the ED

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- hepatic dysfunction
- not capable of reporting their NRS during presentation
- chronic use of analgesics

Study design

Design

Study type: Observational non invasive

Intervention model: Other

Allocation: Non-randomized controlled trial

Control: N/A, unknown

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 22-01-2018

Enrollment: 168

Type: Anticipated

Ethics review

Positive opinion

Date: 17-01-2018

Application type: First submission

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 NL6572 NTR-old NTR6958 Register ID

Other : W18_015. METC, AMC, Amsterdam

Study results