

# High Loading Dose of Paracetamol in the Emergency Department

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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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Other condition
<b>Study type</b>	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:** Emergency 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**

### **Public**

Universitair Medisch Centrum Groningen

Hanzeplein 1  
Groningen 9713 GZ  
NL

### **Scientific**

Universitair Medisch Centrum Groningen

Hanzeplein 1  
Groningen 9713 GZ  
NL

## **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