Acetylcysteïne Dosing in acute PARacetamol intoxication

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22271

Source
Nationaal Trial Register

Brief title
ADPAR

Health condition

Acute paracetamol intoxication

Sponsors and support

Primary sponsor: UMCG
Source(s) of monetary or material Support: academic

Intervention

Outcome measures

Primary outcome

Proportion of moderate (PCM4 = 100 - 150 mg/L), severe (PCM4 = 150-300 mg/L) or massive acute paracetamol intoxications (PCM4 > 300 mg/L).

Secondary outcome

- Which dosing regimens for acetylcysteine are used in the Netherlands (this will be done using a survey to Dutch hospital pharmacists and is not a part of this research protocol).
- In moderate, severe or massive acute paracetamol intoxications:
o Proportion of cases where treatment was prolonged after 24hrs
o Proportion of cases with hepatotoxicity (peak ALT > 1000 U/L)
o Proprotion of cases that have been liver transplanted
o Proportion of fatal cases due to acute paracetamol intoxication
o Proportion of cases with altered INR
o Proportion of cases with adverse events to acetylcysteine that necessitate other treatment
o Proportion of cases with manageable adverse event to acetylcysteine
- Possible association between PCM4 and secondary outcome parameters (treatment duration, hepatoxicity, liver transplantation, fatalities, altered INR)
- Possible association between acetylcysteine treatment regimen and adverse events (manageable and events that necessitate other treatment)

Study description

Background summary

• Background
The antidote in paracetamol overdose is acetylcysteine. Different regimens for dosing of acetylcysteine exist. The most effective dose is unknown.
• Main research question
We want to investigate which acetylcysteine dosing regimens are applied in the Netherlands. We want to investigate what proportion of Dutch acute paracetamol intoxications is moderate (paracetamol level at 4 hrs after ingestion (PCM4) = 100-150 mg/L), severe (PCM4 = 150-300 mg/L) or massive (PCM4 > 300 mg/L). Of these moderate, severe and massive paracetamol intoxications, in what proportion of intoxications is treatment prolonged after 24 hrs, adverse events of acetylcysteine have occurred, hepatotoxicity (peak ALT > 1000 U/L) has occured, liver transplantation has taken place or death has occurred.
• Design (including population, confounders/outcomes)
Observational retrospective study
• Expected results
We expect to gain insight into effective (non toxic) acetylcysteine dosing in acute paracetamol intoxication.

Study objective

We think that not every patient with a paracetamol intoxication might need the high dose of acetylcysteïne antidote we are used to dose in the Netherlands

Study design

Data collection is expected to take 2 years if all Dutch hospitals might participate.

Intervention

none, it is a retrospective observational study

Contacts

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Eligibility criteria

Inclusion criteria

Patients with a serum level of paracetamol that is above the LOQ (5 or 10 mg/L).

Exclusion criteria

Patients that have opted out from data collection

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2020
Enrollment:	2000
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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	NL8862
Other	METC UMCG : METC 2020-374 (non-WMO declaration)

Study results