Pharmacokinetics of single-dose administration of paracetamol by nasoduodenal tube throughout childhood

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o To develop a population PK model *based on the observed concentrations of paracetamol and metabolites after duodenal administration throughout childhood (0-18 years) -to simulate a dosing regimen. The emphasis will be on the early phase of the...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON45360

Source
ToetsingOnline

Brief title
PARADUO

Condition

- Other condition

Synonym
fever, Pain

Health condition

Pijn of koorts waarbij paracetamol gegeven wordt via de duodenale sonde bij kinderen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: children, duodenal tube, paracetamol, pharmacokinetics

Outcome measures

Primary outcome

concentration-time profiles of paracetamol. The study parameters will be

primary PK parameters (clearance and volume of distribution)

Secondary outcome

nvt

Study description

Background summary

Paracetamol is an effective analgesic and antipyretic and is commonly prescribed to treat mild-moderate pain or fever in neonates and children. Paracetamol can be administered orally, rectally, intravenously or by duodenal tube. The last 10 years, PK studies have been conducted for the first mentioned 3 routes of administration in the pediatric population which resulted in different PK parameters (e.g. clearance and volume of distribution) compared to adults; leading to different dosing regimens in the pediatric population. However,nothing is yet known about the PK of paracetamol over the pediatric age-span following paracetamol administration by the duodenal tube, despite the fact that this route is commonly used in the Intensive Care Unit setting.

Study objective

o To develop a population PK model *based on the observed concentrations of paracetamol and metabolites after duodenal administration throughout childhood (0-18 years) -to simulate a dosing regimen.
The emphasis will be on the early phase of the concentration time curve where absorption takes place -to see if there will be a lag in absorption after duodenal administration.

o To evaluate to what extent this newly suggested dosing regimens differs from the currently used dosing regimen.
Paracetamol hereby serves as a model compound to explore potential impact if duodenal compared to oro-gastric administration.
o To further investigate if this developed dosing regime is the same as the one now used for paracetamol duodenal administration in clinical practice.
* to compare the PK parameters derived from the duodenal administration with information derived from IV administration of PK paracetamol studies in the same age-span (IV data is already available)

Study design

this is a population pharmacokinetic study and will be conducted in a single centre non-randomized open label single dose design

Study burden and risks

The potential adverse effects of paracetamol are mild. Dosing is based on the Dutch*s Children*s Formulary. Furthermore paracetamol is administered through the duodenal tube, as clinical care. As there is a lot of experience with duodenal administration of paracetamol, we consider the risks as very low. This practice has even already been reported in the microdosing studies. The only additional burden for the patient will be the additional blood sampling. To minimize the burden there will be: 1) random sampling 2) minimal volume 3) sampling will be taken from the already available arterial or venous line (line present as part of clinical care). The maximum blood volume samples per patient will not exceed 5% of circulating total blood volume (the estimated total blood volume is 80 ml/kg); this sample volume is considered safe and is commonly used in pediatric studies. Another matter is that paracetamol liquid solution will be administered through the duodenal tube whereas it is registered for oral administration. However, the risk is considered to be minimal as there is already a lot of experience from the clinical care with administrating paracetamol through the duodenal route and one of the recommendations of the handbook enteralia is to administer paracetamol solution through a tube. Overall we consider the risks and burden as (very) low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

parenteral informed consent (children 12-18 years of age also informed consent from themselves)
age 0-18 years of age
arterial or venous line
receiving paracetamol through duodenal tube

Exclusion criteria

no informant consent
no ongoing enteral feeding through the nasoduodenal tube
no baseline paracetamol sample has been taken before the paracetamol dosage

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2017
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	20-06-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL59880.078.17