The pharmacokinetics of intravenous salbutamol in pediatric status asthmaticus: a pilot study.

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The primary objective is to explore the pharmacokinetic parameters of intravenous salbutamol in pediatric patients admitted to the intensive care unit. Secondary objectives are to explore a possible relationship between dose, plasma levels,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational invasive

Summary

ID

NL-OMON37955

Source
ToetsingOnline

Brief title
The pharmacokinetics of intravenous salbutamol.

Condition

- Bronchial disorders (excl neoplasms)

Synonym
acute severe asthma, status asthmaticus

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Sophia stichting

Intervention

Keyword: Pediatric Intensive Care Unit, Pharmacokinetics, Salbutamol

Outcome measures

Primary outcome

The main study parameter is the description of the pharmacokinetic parameters

of intravenous salbutamol.

Secondary outcome

Secondary study parameters are the efficacy (asthma scores) and safety

(occurrence of side-effects) of intravenous salbutamol.

Study description

Background summary

In children, the standard therapy for a severe status asthmaticus, unresponsive to inhaled bronchodilators and systemic corticosteroids, is intravenous salbutamol. Although intravenous salbutamol is frequently used in children in a wide range, pharmacokinetic data are scarce. To date, there are insufficient data to guide initial and subsequent dosing recommendation for its intravenous use in children. Especially the need for a loading dose needs to be addressed. Therefore, pharmacokinetic data are needed to guide initial dosing strategies of intravenous salbutamol in children. Because we will not have enough plasma salbutamol concentrations before start of intravenous salbutamol we want to extent the study and determine plasma salbutamol concentrations before and one hour after the start of salbutamol nebulisation.

Study objective

The primary objective is to explore the pharmacokinetic parameters of intravenous salbutamol in pediatric patients admitted to the intensive care unit.
Secondary objectives are to explore a possible relationship between dose, plasma levels, bronchodilating effects and side effects of intravenous salbutamol and to design initial dosing guidelines to optimize intravenous salbutamol therapy in children with severe asthma.

Study design

A pilot population pharmacokinetic-pharmacodynamic study.

Study burden and risks

Patients will be treated according to the standard management protocol of status asthmaticus. Two
blood samples will be taken together with bloodsampling for clinical purposes and will be used for pharmacokinetic analysis. The study can only be carried out in this population as pharmacokinetic results from adults or healthy children cannot be extrapolated to children with status asthmaticus.

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

Age 0 to 18 years-admitted to the hospital because of status asthmaticus- Need for continuous salbutamol nebulisation (more than 3 times/ hour)- Patient/parental informed consent

Exclusion criteria

- Withdrawal of informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-09-2011
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	14-12-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	04-04-2012
Application type:	Amendment
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	NL34232.078.10