DOSING AND PHARMACOKINETICS OF INTRAVENOUS AMOXICILLIN IN CHILDREN

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1) Formulating a dose regimen for intravenous infusion of amoxicillin 1) More insight into the pharmacokinetics of amoxicillin in children of ages making more specific dosing possible.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON32761

Source
ToetsingOnline

Brief title
dosing/pharmacokinetics of intravenous amoxicillin in children

Condition

- Bacterial infectious disorders

Synonym
bacterial infectious diseases; bacterial infections

Research involving
Human

Sponsors and support

Primary sponsor: Canisius Wilhelmina Ziekenhuis
Source(s) of monetary or material Support: Canisius Wilhelmina Ziekenhuis

Intervention

Keyword: amoxicillin, children, dosing, pharmacokinetics

Outcome measures

Primary outcome

Primary parameters in this study will be:

* T1/2 (half-life during elimination phase) and Vss (volume of distribution in steady state) of amoxicillin

* Total body clearance, AUC (area under the time-concentration curve), MRT (mean residence time)

Interpretation of pharmacokinetic parameters

* Plasma concentrations and the AUC*s of amoxicillin will be compared to the MIC (minimal inhibitory concentration) of the microbe to be eliminated.

* T1/2 of amoxicillin will be related to the GFR (glomerular filtration)

* All pharmacokinetic parameters will be related to the personal characteristics of the subjects

Finally, all data will lead to a new dosing advice on intravenous amoxicillin treatment in children.

Secondary outcome

not applicable

Study description

Background summary

Amoxicillin is a bactericide aminopenicillin that is active against gram-positive and gram-negative organisms and also inhibits β-lactamase-free

strains of H. influenzae, N. gonorrhoea, E. coli, Proteus mirabilis and Salmonella species. In paediatrics amoxicillin is used in the treatment of neonatal infections, pneumonias and as a prophylaxis after gastro-intestinal surgery. Despite this wide use, records from our pharmacy show that, when using nationwide dosing regimens like the Kinderformularium®, some children receive higher doses compared to adults. In particular children with a high body mass index and children above 12 years of age are given high doses amoxicillin. This population could be overdosed, unnecessarily. Current literature on pharmacokinetics of amoxicillin use in children is limited to neonates and the use of amoxicillin for specific indications. There are no pharmacokinetic studies about amoxicillin in older children despite the vulnerability of children. In this particular age group it is of great importance to dose with care in order to reach effective levels without exposing them to high doses. This study will clarify dosing of amoxicillin in children measuring the plasma levels and comparing them with the MIC needed to eradicate the micro-organisms causing infection. By calculating the pharmacokinetics as well, we will be able to formulate a new dosing regimen for the use of continuous intravenous infusion of amoxicillin. We expect lower dosing to be possible, in particular in obese children and children above 12 years of age.

Study objective

1) Formulating a dose regimen for intravenous infusion of amoxicillin

1) More insight into the pharmacokinetics of amoxicillin in children of ages making more specific dosing possible.

Study design

Observational study

Study burden and risks

Burden
- 3 blood punctures or an extra indwelling needle or three capillary punctures
- total blood taken: 0,85 ml over 5 days

Risks
- pain and fear: will be reduced by using an anesthetic liniment en good preparation by nurses.
- haematoma
- in neonates: anemia, though not expected because of minimal blood taken and spread over 5 days

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

1. Patients who receive intravenous treatment with amoxicillin
2. Patients < 18 years
3. Written informed consent from the patient and/or their legal guardian

Exclusion criteria

Patients with a known allergy to amoxicillin or related compounds

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2010
Enrollment:	70
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	amoxicillin
Generic name:	amoxicillinum
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	17-02-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2009-016147-19-NL
CCMO	NL29930.091.09