Saliva and serum concentrations of fluconazole in children

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Are fluconazole saliva levels representative for serum levels in children and neonates?

Ethical review	Approved WMO
Status	Pending
Health condition type	Fungal infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON31910

Source
ToetsingOnline

Brief title
Saliva and serum concentrations of fluconazole in children

Condition

- Fungal infectious disorders

Synonym
(invasive) Candida infection, yeast infection

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: children, fluconazole, saliva, serum

Outcome measures

Primary outcome

-pharmacokinetics of fluconazole in saliva and serum in children and neonates

-fluconazole saliva/serum concentration ratio in children and neonates.

Secondary outcome

-Efficacy of fluconazole treatment, as measured by negative

(surveillance-)cultures.

-Does fluconazole reach sufficient levels in the gastrointestinal tract when

the administration route is intravenous

Study description

Background summary

Amongst children treated in the Beatrix Kinderkliniek (BKK) there are patients, who are particularly prone to invasive Candida infections with a high risk for extra morbidity and mortality.[1]
Fluconazole is widely used for treatment of (systemic) yeast infections.[2] It is also used as prophylaxis in children who are at risk for developing candidiasis when they are colonised with Candida species.
Monitoring fluconazole concentrations in different body-fluids is indicated in these patients.
Fluconazole concentration levels can be measured in saliva and there might be a good correlation with serum concentration levels.[5,6] However, this has rarely been studied in adults [6] until now and never in children.
We hypothesize that fluconazole saliva levels correlate with serum levels in children and neonates and can be used for treatment monitoring.

Study objective

Are fluconazole saliva levels representative for serum levels in children and neonates?

Study design

Prospective observational pharmacokinetic study.

Study burden and risks

Burden to the patient will be that he/she has to chew/suck on a small piece of cotton for 1-2 minutes. There are no extra risks associated with participation in this study.

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

Included are children on oral (with of without enteral tube) or intravenous fluconazole

treatment.

Exclusion criteria

Excluded are children from whom it is impossible to get saliva ,or who have, due to their condition, such a serious mucositis of their oral cavity that saliva is mixed with blood, are excluded.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2008
Enrollment:	32
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Diflucan
Generic name:	fluconazole
Registration:	Yes - NL intended use

Ethics review

Approved WMO

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	EUCTR2008-003198-42-NL
CCMO	NL23369.042.08