Modelling of saliva gentamicin concentrations in neonates receiving gentamicin treatment

Published: 27-08-2018
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Primary objective:To establish whether saliva samples could be used as an alternative for blood samples in the therapeutic drug monitoring for gentamicin. To meet this objective, a PK model will be developed for gentamicin saliva concentrations....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON48679

Source
ToetsingOnline

Brief title
Saliva gentamicin concentration in neonates

Condition

- Bacterial infectious disorders

Synonym
antibiotic treatment

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Gentamicin, Neonates, Saliva, Therapeutic drug monitoring

Outcome measures

Primary outcome

Primary study paramters are the saliva gentamicin concentrations at different time-points.

Secondary outcome

Secundary study parameters of this study are gentamicin concentrations in plasma, correlation between plasma and saliva gentamicin, citric acid stimulation during saliva sampling (Y/N), sampling duration, salivary pH and sample volume.

Study description

Background summary

In neonatology wards, neonates are often admitted due to suspected infection. In the Netherlands, neonatologists often prescribe the aminoglycoside antibiotic gentamicin. Gentamicin has a small therapeutic index and therefore, therapeutic drug monitoring has to be performed. This is done by taking two blood samples (peak and trough levels), which causes a considerable burden for the neonate. Therefore, a non-invasive method of therapeutic drug monitoring, for example in saliva, would be preferred.
An earlier study has demonstrated a good correlation between saliva and plasma gentamicin concentrations in children receiving a once-daily gentamicin infusion.
This study aims to determine a correlation between saliva and serum gentamicine concentrations in different neonatal subgroups. We will use population PK modelling techniques to fit a model and use this model to calculate serum gentamicin concentrations.

Study objective

Primary objective:

To establish whether saliva samples could be used as an alternative for blood samples in the therapeutic drug monitoring for gentamicin. To meet this objective, a PK model will be developed for gentamicin saliva concentrations.

Secondary objective:
To describe the relation between the saliva PK model and the plasma PK model.
To reduce the number of invasive blood samples in this fragile poulation.

Study design

Observational non-interventional study using gentamicin concentration measurements from saliva samples and clinically planned plasma gentamicin measurements. Additional measurements of gentamicin levels in plasma will be taken from leftover material.

Study burden and risks

The peak- and through serum gentamicin concentrations are determined according to clinical routine. These samples are obtained from either indwelling catheters or from venous blood sampling procedures. No additional blood samples are scheduled for this study.
The saliva samples are drawn using the SalivaBio Infant's Swab. These swabs are designed specifically for the collection of saliva of young infants and can be held during sampling, eliminating the risk of asphyxiation. The time-points of saliva sampling are paired with clinical routine (i.e. before feeding), so that the infants are not disturbed more frequently when participating in this study.
This study will provide information concerning the possibility to perform therapeutic drug monitoring of gentamicin in neonates using saliva gentamicin concentrations. If this is found to be a valid alternative, it will be no longer required to draw blood from neonates for therapeutic drug monitoring of gentamicin in the future.
This study concerns a specific population with specific characteristics. Therefore, it is not possible to conduct this study in adult patients or test animals.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Gentamicin treatment
Admission to the neonatology ward , pediatrics/pediatric surgery department, obstetrics department or maternity ward of the AMC/Juliana children*s hospital (Haga Hospital)
Signed informed consent from both parents prior to any study-mandated procedure

Exclusion criteria

Congenital disease of the salivary glands
Parent refusal
Inability to sample saliva

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-10-2018
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	27-08-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-05-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL66410.018.18