Levels Lidocaine in the Newborn after an Episiotomy given to the Mother

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Foetal complications
Study type	Observational non invasive

Summary

ID

NL-OMON40012

Source
ToetsingOnline

Brief title
KLEM

Condition

- Foetal complications

Synonym
anaesthetic during birth, perinatal transmission of lidocaine

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: eigen financiering

Intervention

Keyword: episiotomy, lidocaine, newborn

Outcome measures

Primary outcome

The level lidocaine in the newborn on time of delivery and the level lidocaine

in the mother on time of delivery.

Secondary outcome

The range of lidocaine levels in 24 hours in the newborn.

Study description

Background summary

Lidocaine is administered to the mother as local anesthetic before performing a surgically planned incision to the perineum (episiotomy) during delivery.
In Amphia Hospital two cases have been presented with a possibility of intoxication with lidocaine, following medical signs. Levels could not exclude an incorrect gift of lidocaine via the maternal perineum directly in the head skin of the child, or a concentration caused by transmission via the maternal blood when it was administered locally to the mother.
Transmission of lidocaine to the child via the umbilical cord is possible. To define exactly when an intoxication will occur in newborns, it is necessary to determine the lidocaine concentrations in a child after delivery when lidocaine is locally administrated to the mother. It is also interesting to look at the interval between administration of lidocaine and the time of delivery in relation to the degree of transmission of lidocaine to the child. In the current literature, no relation could be confirmed between the concentration lidocaine in the newborn and the interval between administration and partus.
Beside this, it is important to know the pharmacokinetics of lidocaine in newborns. By research the pharmacokinetics of lidocaine in newborns, we can estimate the duration of exposure to lidocaine and the estimated level of lidocaine belonging to a specific time.
We aim to investigate the transmission of lidocaine from mother to child during delivery and study the pharmacokinetics of lidocaine in newborns.

Study objective

With this study we want to determine the concentration lidocaine in newborn after partus using an episiotomy in relation to the concentration in mother. Our secondary objectives are to look at the relation between the degree of transmission of lidocaine to the newborns and the drug-delivery interval, and the pharmacokinetical behaviour of lidocaine in newborn after transmission of lidocaine during the partus.

Study design

Prospective observational cohort study

Study burden and risks

Women are asked for participation in the study and at the time the child is delivered, about 100 microliter blood of the mother is obtained to measure a lidocaine level. This risk is absent, when blood can obtained from an intravenous line.
When the umbilical cord is clamped, venous and arterial blood will be obtained from the umbilical cord. No burden is associated with this intervention.
Minimal 100 microliter blood of the neonate is obtained at five predefined times. The burden for these neonates is minimal, because they will, according current practice, obtain blood at five predefined times for determine glucose curves.
There are no benefits for the participants. The result of the study may contribute to increase of acknowledgement about drugs administered to pregnant women, the risk of transmission to the child and the behaviour of lidocaine in the neonate.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

informed consent
delivery in Amphia Hospital
local administration of lidocaine
gestation period from 32 weeks
for newborn also stay in hospital for determine a glucose curve

Exclusion criteria

administration of lidocaine for other purposes than local anesthesia
administration of epinephrine together with lidocaine for episiotomy

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-02-2013
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	18-01-2013
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21641
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL42283.015.12
OMON	NL-OMON21641