KLEM-studie.

Gepubliceerd: 19-12-2012 Laatst bijgewerkt: 15-05-2024

There will be a relation between the level lidocaine in newborn, the level in mother and drug-delivery interval.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21641

Bron
Nationaal Trial Register

Verkorte titel
KLEM

Aandoening

perinatale transmissie van lidocaïne

perinatal transmission of lidocaine

Ondersteuning

Primaire sponsor: Amphia Hospital
Overige ondersteuning: Amphia Hospital

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Plasma concentration lidocaine in the newborn and in the mother on time of delivery.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

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.

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 population:

Fourty obstetrical women with lidocaïne for local anesthesia before episiotomy at partus and within this group, all eligible

newborns (minimal 6, maximal 18) who had to stay in the hospital for determine a glucose curve.

Primary study parameters/outcome of the study:

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

Secundary study parameters/outcome of the study:

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

Doel van het onderzoek

There will be a relation between the level lidocaine in newborn, the level in mother and drug-delivery interval.

Onderzoeksopzet

1. t=0 hour at delivery;

2. For newborn: t=1, t=3, t=6, t=12, t=24 hour.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Informed consent;

2. Delivery in Amphia Hospital;

3. Administration of lidocaine in the perineum for local anesthesia;

4. Gestation period from 32 weeks;

5. For the newborn: stay in the hospital to determine glucose levels.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Administration of lidocaine for other purposes than local anesthesia;

2. Administration of epinefrine together with lidocaine for episiotomy.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2013
Aantal proefpersonen:	40
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	19-12-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40012
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3602
NTR-old	NTR3761
CCMO	NL42283.015.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON40012

Resultaten

Samenvatting resultaten
N/A