Intrauterine resuscitation during term labor by maternal hyperoxygenation: a pilot study

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21613

Source
NTR

Brief title
INTEREST-O2

Health condition

Fetal distress, maternal hyperoxygenation, labor, intrauterine resuscitation.

Sponsors and support

Primary sponsor: Maxima Medical Center, Veldhoven, The Netherlands.
Source(s) of monetary or material Support: Stichting de Weijerhorst (partial), Board of Management Máxima Medical Center Veldhoven.

Intervention

Outcome measures

Primary outcome

The primary outcome measure is FHR pattern (frequency, depth and duration of decelerations, baseline and variability).

Secondary outcome

Secondary outcome measures are arterial and venous umbilical cord pH, base excess, lactate, pO2 and pCO2, Apgar score, mode of delivery, neonatal intensive care unit (NICU) admission, markers for free oxygen radical production and maternal side effects of oxygen admission and reasons for discontinuation.

Study description

Background summary

Rationale: Perinatal asphyxia is one of the four main causes of perinatal morbidity and mortality in the Netherlands. During labor, continuous fetal heart rate monitoring is used to estimate fetal wellbeing. When a fetal heart rate pattern is nonreassuring, this may be a sign of fetal hypoxia. Prolonged fetal hypoxia may lead to perinatal asphyxia. Small human studies of moderate quality do indicate that additional oxygen supplied to the mother in case of fetal distress improves fetal heart rate pattern and fetal oxygenation. In the United Stated of America maternal hyperoxygenation in case of fetal distress is common practice and recommended by the American College of Obstetricians and Gynecologists . However, the British guideline recommends not to use additional oxygen for fetal distress because of the lack of randomized studies proving its beneficial effect, and the potentially harmful effect of increased free oxygen radical production. The Dutch guideline did not propose any recommendation yet. Several important reviews conclude that there is an urgent need for a randomized controlled trial investigating the effect of maternal hyperoxygenation on fetal condition. We hypothesize that the beneficial effects on fetal oxygenation outweighs the potential increase in free oxygen radical production. Objective: To investigate the effect of maternal hyperoxygenation with 100% oxygen on fetal heart rate pattern, during the second stage of labor in case of suspected fetal distress. Study design: Single-center randomized controlled trial in a tertiary hospital in the Netherlands (Máxima Medical Center). Study population: 116 healthy women, giving natural birth at term, to a singleton healthy fetus in cephalic presentation. Intervention: In case of suboptimal or abnormal FHR patterns (according to the FIGO classification) during the second stage of labor, 100% oxygen is applied to the mother by a non-rebreathing mask, and continued until delivery. Main study parameters/endpoints: the primary outcome measure is FHR pattern (frequency, depth and duration of decelerations, baseline and variability). Secondary outcome measures are arterial and venous umbilical cord pH, base excess, lactate, pO2 and pCO2, Apgar score, mode of delivery, neonatal intensive care unit (NICU) admission, markers for free oxygen radical production and maternal side effects of oxygen admission and reasons for discontinuation.

Study objective

We expect maternal hyperoxygenation in the presence of fetal distress during labor to reduce abnormalities in the fetal heart rate tracing and to reduce the need for assisted birth or a emergency caesarean section without severe maternal or fetal side effects.

Study design

The outcome measures will be recorded during the second stage of labor.

Intervention

In case of suboptimal or abnormal FHR patterns (according to the FIGO classification) during the second stage of labor, 100% oxygen is applied to the mother by a non-rebreathing mask, and continued until delivery.

Contacts

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Eligibility criteria

Inclusion criteria

Maternal factors:

- Age > 18 years

- In term labor (gestational age 37+0 - 41+6 weeks)

- Intention for vaginal delivery

- Ability to understand the Dutch or English language

- Informed consent obtained

Fetal factors:

- Singleton fetus

- Fetus in cephalic presentation

- Suboptimal or abnormal FHR pattern
(according to FIGO classification, with exception of prolonged fetal bradycardia)

Exclusion criteria

Maternal factors:

- Age < 18 years

- Use of any of the following medication: corticosteroids, antihypertensives, magnesiumsulphate, amiodaron, opioids, adriamycine, bleomycine, actinomycine, menadion, (chloor-) promazine, thiordiazine, chloroquine.

- Pre-existing cardiac disease

- Pulmonary disease needing the use of medication

- Diabetes

- Hyperthyroidism

- Anemia (Hb < 6.5 mmol/l)

- Smoking, using alcohol or recreational drugs during pregnancy

- Pre- or postterm labor (< 37+0 or > 41+6 weeks)

- Planned caesarean section

Fetal factors:

- Multiple fetuses

- Suspected infection

- Congenital malformations

- Breech presentation

- Normal or preterminal FHR pattern, or prolonged fetal bradycardia (according to FIGO classification)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2015
Enrollment:	116
Type:	Actual

Ethics review

Positive opinion

Date:	20-10-2015
Application type:	First submission

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
NTR-new	NL5351
NTR-old	NTR5461
Other	NL53018.015.15 CCMO : 2015-001654-15 EUDRA CT

Study results

Summary results
Interventions for Intrauterine Resuscitation in Suspected Fetal Distress During Term Labor: A Systematic Review.
Bullens LM, van Runnard Heimel PJ, van der Hout-van der Jagt MB, Oei SG.
Obstet Gynecol Surv. 2015 Aug;70(8):524-39.

A simulation model to study maternal hyperoxygenation during labor.
Bullens LM, van der Hout-van der Jagt MB, Van Runnard Heimel PJ, Oei G.
Acta Obstet Gynecol Scand. 2014 Dec;93(12):1268-75.