Intrauterine resuscitation during term labor by maternal hyper oxygenation: a pilot study.

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To investigate the effect of maternal hyperoxygenation with 100% in the second stage of labor and in the presence of abnormal fetal heart rate (FHR) patterns on fetal condition, instrumental delivery rate and free radical production. In case a...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Interventional

Summary

ID

NL-OMON44980

Source
ToetsingOnline

Brief title
INTEREST-O2

Condition

- Pregnancy, labour, delivery and postpartum conditions

Synonym
nonreassuring fetal condition, Suspected fetal distress

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Stichting de Weijerhorst

Intervention

Keyword: Fetal distress, Intrauterine resuscitation, Maternal hyperoxygenation

Outcome measures

Primary outcome

The primary outcome measure is fetal heart rate pattern (frequency, depth and duration of decelerations).

Secondary outcome

Secondary outcome measures are umbilical cord (arterial and venous) pH, base excess, lactate, pO2 and pCO2, Apgar-score, mode of delivery, neonatal intensive care unit admission, markers for free oxygen radical production in umbilical cord blood and fetal ECG. Experience of participants with participating in this study.

Study description

Background summary

Perinatal asphyxia is one of the four main causes of perinatal morbidity and mortality in the Netherlands. Small human studies of poor quality do indicate that additional oxygen supplied to the mother in case of fetal distress improves fetal condition during labor. In the USA 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 potentially harmfull effect of increased free-radical production. The Dutch guideline did not propose any recommendation yet. Several reviews conclude that there is an urgent need for a randomized controlled trial investigating the effect of maternal hyperoxygenation on fetal condition. We hypothesise that the beneficial effects on fetal oxygenation outweighs the potential increase in free-radical production.

Study objective

To investigate the effect of maternal hyperoxygenation with 100% in the second stage of labor and in the presence of abnormal fetal heart rate (FHR) patterns on fetal condition, instrumental delivery rate and free radical production. In case a positive effect on FHR pattern is shown, we will use the data obtained from this study to design a larger, multicenter RCT to investigate the effect on umbilical cord pH and/or Apgarscore.

Study design

Randomized controlled trial in a tertiary hospital in the Netherlands.

Intervention

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

Study burden and risks

Continuous FHR monitoring generally takes place through a transvaginal lead attached to the fetal head. This is common practice in all clinical deliveries. The non-rebreathing mask fits tight to the nose and mouth which may cause some discomfort to the parturient. High levels of inspired oxygen may cause reversible vasoconstriction in the mothers brain of approximately 10%. This is not expected to cause any harm. Besides, the amount of free oxygen radicals will increase in the maternal blood. We do not expect this to cause any harm due to the mature anti-oxygen sytem in the adult. We expect the fetus to profit from maternal hyperoxygenation by improved pH levels and a decreased risk on prolonged fetal hypoxia potentially resulting in perinatal asphyxia. In the fetal blood the amount of free oxygen radicals may increase as well. Neonatal resuscitation with 100% oxygen may lead to an increased risk of fetal bronchopulmonary disease and retinopathy, especially in premature infants. However, in this study preterm deliveries are excluded. Besides, the increase in fetal pO2 due to maternal hyperoxygenation will never reach the increase as a result of direct application of 100% oxygen to the fetus.

Besides we hypothesise that less interventions to immediately deliver the fetus, such as episiotomy, assisted vaginal delivery or caesarean sections will be needed. Both mothers and foetuses will profit from this effect.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Maternal factors:
- Age > 18 years
- In term labor (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 head position
- Suboptimal or abnormal CTG

Exclusion criteria

Maternal factors:
- Age < 18 years
- Use of the following medication: corticosteroids, antihypertensives, magnesiumsulphate, amiodaron, 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 foetuses
- Suspected intrauterine infection
- Congenital malformations
- Breech position

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-03-2016
Enrollment:	116
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Medicinal oxygen
Generic name:	Oxygen
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	19-08-2015
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	15-10-2015
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	12-01-2016
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	25-02-2016
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	15-03-2016
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	12-04-2016
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	23-03-2017
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO	

Date:	12-04-2017
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	EUCTR2015-001654-15-NL
CCMO	NL53018.000.15