Knee to chest flexion to reduce respiratory distress after elective caesarean birth: a feasibility study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26395

Source
Nationaal Trial Register

Brief title
RELACS

Health condition

Transient tachypneu of the neonate (TTN), respiratory distress syndrome (RDS)

Sponsors and support

Primary sponsor: NA
Source(s) of monetary or material Support: NA

Intervention

Outcome measures

Primary outcome

Feasibility and safety measures.
Primary outcome will be the success in performing a KCF according to protocol.

Secondary outcome

Secondary outcome will be expulsion of lung fluid and safety parameters: compression of the cord during KCF, Apgar score at 1, 5 and 10 minutes, hematoma on extremities, abdomen and chest, temperature at admission and occurrence of respiratory distress.

Study description

Background summary

Rationale: The respiratory adaptation of term infants born after elective caesarean section (CS) can be problematic and results in unexpected admission to the intensive care within hours of birth. The respiratory distress is usually caused by lung liquid in the airways (wet lung or transient tachypnea of the newborn (TTN)), which can evolve into a more severe respiratory distress and/or pulmonary hypertension of the newborn (PPHN) .

Historically the respiratory distress in term infants after elective CS was thought to result from delayed clearance of lung liquid due to reduced sodium reabsorption. However, there is now physiological pre-clinical evidence that the respiratory distress results from having a greater volume of lung liquid in the airways at birth, causing poorer lung function in the immediate newborn period. The presence of greater lung liquid volumes at birth can result when delivery occurs by elective CS, which avoids exposure of the infant to uterine contractions that normally occur during labour. During labour, uterine contractions force a change in fetal posture, which greatly increases fetal spinal flexion, increasing abdominal pressure, which increases transpulmonary pressure by elevating the diaphragm, resulting in lung liquid loss via nose and mouth. As labour is absent during elective caesarean section, infants are born with a larger volume of lung liquid and all of this liquid must be cleared across the distal airway wall into lung tissue. While this airway liquid is rapidly replaced by air as soon as breathing starts, the presence of large volumes of liquid in lung tissue (akin to pulmonary oedema) adversely affects lung function and increases the tendency for liquid reflood the airways, leading to respiratory problems.

This new finding offers a new opportunity to adopt interventions that can reduce the lung liquid volume and thus reducing the related respiratory problems. We hypothesize that flexion induced by uterine contractions can be mimicked by manually performing a knee-to-chest flexion (KCF) leading to spinal flexion directly at birth while the infant is held in dorsoflexion in order to facilitate expulsion of lung liquid and to reduce the net lung liquid that the infant needs to clear after birth. This will ultimately decrease the risk for respiratory distress.

So far, no studies have been performed using this new approach, but it has the potential to reduce the incidence of respiratory distress after elective caesarean for which admission to intensive care is needed. We will firstly perform a pilot study to test a) whether it is possible to perform a KCF manoeuvre directly after birth and b) whether we can observe expulsion

lung liquid.

Study objective

We hypothesize that flexion induced by uterine contractions can be mimicked by manually performing a knee-to-chest flexion (KCF) leading to spinal flexion directly at birth while the infant is held in dorsoflexion in order to facilitate expulsion of lung liquid and to reduce the net lung liquid that the infant needs to clear after birth. We hypothesize that the reduction of lung fluid volume that will be generated by this manoeuvre will ultimately decrease the risk for respiratory distress in term infants born after cesarean section.

Study design

First minute after birth

Intervention

Knee to chest flexion (KCF)

Contacts

Public
Leids Universitair Medical Center
Anne Marie Keus

071-5262824
Scientific
Leids Universitair Medical Center
Anne Marie Keus

071-5262824

Eligibility criteria

Inclusion criteria

Infants are eligible when they are born by elective CS at 37-42 weeks gestational age.
In case of twin pregnancies, only the second born infant will be included

Exclusion criteria

-significant congenital malformations influencing cardiopulmonary transition,
-first born infants in twin pregnancies,
-infants where immediate cord clamping is needed,
-when spontaneous contractions before CS occur.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2021
Enrollment:	41
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
NA

Ethics review

Positive opinion

Date:	15-01-2021
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	NL9201
Other	METC Leiden Den Haag Delft : METC LDD p20.115

Study results

Summary results
NA