

Knee to chest flexion to reduce respiratory distress after elective caesarean birth: a feasibility study (REducing Lung liquid After Caesarean Section; RELACS-study)

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To test whether performing a knee-to-chest flexion (KCF) manoeuvre is feasible directly at birth in infants born after elective caesarean section (CS) and leads to clearance of excess of lung liquid. Also safety parameters for mother and child will...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal respiratory disorders
Study type	Interventional

Summary

ID

NL-OMON55113

Source

ToetsingOnline

Brief title

ReLACS

Condition

- Neonatal respiratory disorders

Synonym

dyspnea, transient tachypnea of the newborn (TTN)

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: elective caesarean, neonate, respiratory distress

Outcome measures

Primary outcome

Primary outcome is the occurrence of a KCF performed and completed according to protocol.

Secondary outcome

Safety parameters during KCF:

- * Compression of the cord during KCF
- * Any Hematoma on extremities, abdomen or chest within 24 hours after birth
- * The occurrence a KCF where expulsion of lung liquid during KCF is observed
- * The occurrence of respiratory distress (TTN, RDS, PPHN) for which respiratory support at birth and/ or NICU admission for respiratory support in the first 24 hours of life is needed.

Other parameters:

- * Breech or head delivery
- * How often KCF could be performed (in total group of included patients)
- * How often KCF was adequately performed (in total group of included patients)
- * Duration (in seconds) between delivery of head and start of KCF
- * Duration (in seconds) of KCF

- Duration (in seconds) between delivery of the head and first vigorous breath

Study description

Background summary

We hypothesise that, considering the increasing rates of CS worldwide this simple method to reduce excess airway liquid in infants born after elective CS, before the available large liquid volumes can cause respiratory problems, has a potential to decrease the burden of respiratory problems in this group of infants.

Study objective

To test whether performing a knee-to-chest flexion (KCF) manoeuvre is feasible directly at birth in infants born after elective caesarean section (CS) and leads to clearance of excess of lung liquid.
Also safety parameters for mother and child will be looked at.

Study design

Single centre prospective interventional study

Intervention

Immediately after infants are extracted from the uterus, a KCF will be performed before vigorous breathing of the infant has commenced. The obstetrician will place one hand in the neck and shoulder of the baby and gently bend the infant into dorso-flexion while with the other hand bending the hips and knees against the abdomen and chest (squatting into fetal position). This holding position will be continued for 45 seconds, while compression of the umbilical cord is avoided to maintain an undisturbed umbilical circulation to and from the infant during KCF. The technique used will be similar to the position an infant is held during lumbar puncture.

During KCF the infant will remain attached to the cord and receive standard care, which means it will be covered with gauze to prevent hypothermia and be held as close as possible to the mother. After 45 seconds the KCF will be terminated, allowing the infant to start breathing and resuming routine care provided to all infants after CS.

Study burden and risks

The KCF, as a so called extra-uterine contraction, is a non-invasive, short intervention and mimicks the fetal position in which a neonate is positioned during intra-uterine contractions. As the study population only contains healthy term neonates, the burden and risk associated with participation is expected to be minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Newborns

Inclusion criteria

Healthy term infants born after elective caesarian section.

Exclusion criteria

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

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 30-03-2021

Enrollment: 41

Type: Actual

Ethics review

Approved WMO

Date: 26-01-2021

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO

Date: 03-09-2021

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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
CCMO	NL74285.058.20