Compressive force applied to the head during face mask ventilation in the delivery room and its influence on cerebral oxygenation

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To investigate the compressive force applied to the head during face mask ventilation in the delivery room and to determine whether this force has influence on cerebral oxygenation.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON38661

Source
ToetsingOnline

Brief title
Force applIed duRing Mask ventilation (FIRM-study)

Condition

- Other condition

Synonym
Brain perfusion, force on the head

Health condition

hersendoorbloeding

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: brain oxygenation, facemask, force, resuscitation

Outcome measures

Primary outcome

Correlation of the amount of force (grams) on the head during neonatal resuscitation with the regional oxygen saturation (%) of the brain.

Secondary outcome

- Correlation of regional oxygen saturation (%) measured at the right arm with regional oxygen saturation of the brain measured at the forehead (%).

- Correlation of major disabilities during admission at the NICU (death, intra-ventricular hemorrhage, periventricular leucomalacia etc.) with the amount of force (grams).

Study description

Background summary

An appropriate mask technique is essential for establishing effective ventilation.(1) Leak between mask and face is common, even for experienced operators, and it reduces the efficacy of resuscitation.(2-4) Also airway obstruction can influence mask ventilation immediately after birth, (3;5) especially in very low birth weight infants as they have a relatively large tongue and small mandibles.(5) While investigating mask ventilation techniques using manikins, we observed that when the resuscitator was notified of mask leak, airway obstruction often accompanied the corrective action.(2) Possibly by applying to much pressure on the head with the face mask.(2) When we

quantified force applied to a manikin*s head during simulated mask ventilation we observed that using a T-piece resuscitator mean (SD) forces of 2028 (909) g was exerted on the head. (6) This equals pressured of 164 (73) mm Hg.(6) Also when the participant was asked to minimize the mask leak in a second attempt similar forces were measured.(6) We speculate that these forces can have significant physiological impact on the blood circulation in the skull. Indeed, as the systemic arterial pressures are only 50*60 mm Hg (at best), (6) we would expect cerebral capillary blood flow to effectively cease in regions exposed to the greatest force and cerebral oxygenation to drop. If the pressures persist, this may cause hypoxic/ischaemic injury as well as increasing the risk hyperperfusion injury following the release of force.

So far force was only measured during simulated resuscitation, but to investigate the force on the head and its effect on cerebral oxygenation an observational study during neonatal resuscitation would be needed.

Study objective

To investigate the compressive force applied to the head during face mask ventilation in the delivery room and to determine whether this force has influence on cerebral oxygenation.

Study design

Observational study

Study burden and risks

All measurements are strictly observational and will not in any way influence the way the infant is treated. Therefore there are no risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Preterm infants requiring resuscitation will be included in this study

Exclusion criteria

Preterm infants with malformation of the head, face or the upper respiratory tract.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-02-2014
Enrollment:	20

Type:	Actual

Ethics review

Approved WMO Date:	27-05-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL43081.058.13