An international multicenter randomized controlled trial of high frequency oscillation versus conventional mechanical ventilation in infants with congenital diaphragmatic hernia: the VICI-trial

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Does treatment with high frequency oscillatory ventilation reduce the incidence of chronic lung disease at day 28 and/or death at day 28 in comparison with conventional mechanical ventilation in new-born children having congenital diaphragmatic...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23312

Bron
NTR

Verkorte titel
The VICI-trial

Aandoening

congenital diaphragmatic hernia/congenitale hernia diafragmatica/ventilation/beademing/neonates/neonaten/newborns/pasgeborenen/chronic lung disease/ bronchopulmonary dysplasia/ bronchopulmonaire dysplasie/high frequency oscillatory ventilation

Ondersteuning

Primaire sponsor: ErasmusMC-Sophia

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Overige ondersteuning: ErasmusMC-Sophia
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Death at day 28 and/or oxygen dependency at day 28

Toelichting onderzoek

Achtergrond van het onderzoek

High frequency oscillatory ventilation is an effective way of providing gas exchange. In animals with severe pulmonary disease, high frequency oscillatory ventilation improves gas exchange, promotes uniform lung inflation, reduces barotrauma and decreases the appearance of inflammatory mediators. Also, high frequency oscillatory ventilation may reduce the severity of lung injury induced by mechanical ventilation.
High frequency oscillatory ventilation has been used in preterm infants with respiratory distress syndrome, either as an elective ventilation strategy or as a rescue therapy when conventional ventilation failed. A Cochrane review, which described the use of elective high frequency oscillatory ventilation compared to conventional ventilation in preterm infants, found no significant differences in mortality and oxygen therapy. Some trials, however, described a significant reduction of chronic lung disease in preterm infants treated with high frequency oscillatory ventilation. A second Cochrane review described the use of high frequency oscillatory ventilation as a rescue therapy when conventional ventilation failed in term and near term infants. Only one trial compared these two ventilation strategies in a prospective way, resulting in no significant difference in outcome, need for extracorporeal membrane oxygenation, or complications.
In children having congenital diaphragmatic hernia the use of high frequency oscillatory ventilation and conventional ventilation have been compared retrospectively. Studies showed significantly improved survival and a lower incidence of chronic lung disease with elective use of high frequency oscillatory ventilation. However, these studies investigated the ventilation strategies in different eras. Therefore, the results might be positively influenced by other medical improvements during the last decades. Other retrospective descriptive studies concluded high frequency oscillatory ventilation to be a safe ventilation strategy in

infants having congenital diaphragmatic hernia.
No prospective randomized controlled trials have been carried out to compare high frequency oscillatory ventilation to conventional ventilation in infants having congenital diaphragmatic hernia. Therefore, a future trial to give a more clear description of the effects of high frequency oscillatory ventilation in children having congenital diaphragmatic hernia is needed.

Doel van het onderzoek

Does treatment with high frequency oscillatory ventilation reduce the incidence of chronic lung disease at day 28 and/or death at day 28 in comparison with conventional mechanical ventilation in new-born children having congenital diaphragmatic hernia ?

Onderzoeksopzet

- Antenatal screening period, prior to enrollment

- Randomization period, within one hour after birth

- Treatment period, depending on cardio respiratory status of the infant

- Observation period, up to day 56 after birth or discharge

- Follow-up period during the first year of life

Onderzoeksproduct en/of interventie

After delivery, the patient will be intubated immediately and receive the allocated ventilation strategy (high-frequency oscillatory ventilation or conventional ventilation). Vital functions will be measured by a monitor. General laboratory measurements, blood gasses and urine samples will be taken regularly according to the standard care on the intensive care unit. An arterial line and a central venous line will be given. X-rays of the thorax will be made on a regular basis. To exclude a vitium cordis and to measure pulmonary hypertension, an echocardiography will be performed and repeated on clinical indication. An echo of the brain will be performed. After the patient has stabilized, surgery will be performed. If necessary, an ECMo procedure will be performed. All the procedures described above are standard procedures in paediatric intensive care medicine. Mostly, every child born with a congenital diaphragmatic hernia will undergo these procedures.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Newborn children antenatally diagnosed with congenital diaphragmatic hernia

2. The children are born in one of the participating centres

3. The children are born at or after a gestational age of 34 weeks

4. Prenatal informed consent

5. High-risk infants who received a fetal intervention may be included

6. Infants small for gestational age may be included

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Infants born with a severe chromosomal anomaly, like trisomy 18 or trisomy 13, which may imply a decision to stop further life-saving medical treatment

2. Infants born with a severe cardiac anomaly, expected to need corrective surgery in the first 60 days of life

3. Infants born with renal anomalies associated with oligohydramnios

4. Infants born with severe orthopaedic and skeletal deformities which are likely to influence thoracic and / or lung development

5. Infants born with severe anomalies of the central nervous system

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2008
Aantal proefpersonen:	400
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1264
NTR-old	NTR1310
Ander register	ErasmusMC-Sophia, METC ErasmusMC : no
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

-Migliazza, L., et al., Retrospective study of 111 cases of congenital diaphragmatic hernia treated with early high-frequency oscillatory ventilation and presurgical stabilization. J Pediatr Surg, 2007. 42(9): p. 1526-32.
-Ng, G.Y., et al., Reduction in ventilator-induced lung injury improves outcome in congenital diaphragmatic hernia? Pediatr Surg Int, 2008. 24(2): p. 145-150.
-Logan, J.W., et al., Mechanical ventilation strategies in the management of congenital diaphragmatic hernia. Semin Pediatr Surg, 2007. 16(2): p. 115-25.
-Cacciari, A., et al., High-frequency oscillatory ventilation versus conventional mechanical ventilation in congenital diaphragmatic hernia. Eur J Pediatr Surg, 2001. 11(1): p. 3-7.
-Bhuta, T., R.H. Clark, and D.J. Henderson-Smart, Rescue high frequency oscillatory ventilation vs conventional ventilation for infants with severe pulmonary dysfunction born at or near term. Cochrane Database Syst Rev, 2001(1): p. CD002974.
-Henderson-Smart, D.J., et al., Elective high frequency oscillatory ventilation versus conventional ventilation for acute pulmonary dysfunction in preterm infants. Cochrane Database Syst Rev, 2007(3): p. CD000104.
-Clark, R.H., et al., Lung injury in neonates: causes, strategies for prevention, and long-term consequences. J Pediatr, 2001. 139(4): p. 478-86.