

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

No registrations found.

| | |
|------------------------------|----------------|
| Ethical review | Not applicable |
| Status | Pending |
| Health condition type | - |
| Study type | Interventional |

Summary

ID

NL-OMON23312

Source

NTR

Brief title

The VICI-trial

Health condition

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

Sponsors and support

Primary sponsor: ErasmusMC-Sophia

P.O. Box 2060

3000 CB Rotterdam

the Netherlands

Source(s) of monetary or material Support: ErasmusMC-Sophia
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Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- Severity of chronic lung disease according to the Bancalari definition:
 - o Determined in children having oxygen use at day 28
 - o Point of assessment of severity of chronic lung disease at day 56 or discharge whichever comes first:
 - § Mild: breathing room air
 - § Moderate: need for < 30 % oxygen
 - § Severe: need for ≥ 30 % oxygen and/or positive pressure by mechanical ventilation or CPAP
- Number of ventilator-free days at day 30
- Number of ventilator-free days at day 60

Study description

Background summary

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.

Study objective

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 ?

Study design

- 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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

| | |
|---------------------|-----------------------------|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

Recruitment

| | |
|---------------------------|-------------|
| NL | |
| Recruitment status: | Pending |
| Start date (anticipated): | 01-10-2008 |
| Enrollment: | 400 |
| Type: | Anticipated |

Ethics review

Not applicable

Application type:

Not applicable

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 | NL1264 |
| NTR-old | NTR1310 |
| Other | ErasmusMC-Sophia, METC ErasmusMC : no |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

Study results

Summary results

- 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.