HERNIA-study: congenital diaphragmatic Hernia, Environment, Retinoids, Nutrition, Inheritance, other Associations

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- To analyze retinoid levels in plasma and amniotic fluid from infants and mothers to establish the potential link between retinoids and CDH. - To establish a registry of blood and tissue samples that will be valuable for future studies of the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON29811

Source
ToetsingOnline

Brief title
HERNIA-study

Condition

- Respiratory disorders congenital
- Neonatal and perinatal conditions

Synonym
hernia; diaphragmatic defect

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Congenital Diaphragmatic Hernia, Etiology, Genetics, Retinoids

Outcome measures

Primary outcome

Primary study parameter is a significant difference in the levels of retinoids

between mothers and children with CDH and healthy mothers/newborns.

Secondary outcome

- A difference in the genetic profile between patients and controls

- Identification of a possible relationship between nutrional and environmental

factors and the etiology of CDH

Study description

Background summary

Congenital diaphragmatic hernia (CDH) is a major life-threatening cause of respiratory failure in the newborn. Our current understanding of the pathogenesis and etiology remains very limited. There is very intriguing evidence suggesting that abnormalities linked with the retinoid signalling pathway early in gestation may contribute to the etiology of CDH. This multicentre study will be pivotal for testing this hypothesis.

Study objective

- To analyze retinoid levels in plasma and amniotic fluid from infants and mothers to establish the potential link between retinoids and CDH.
- To establish a registry of blood and tissue samples that will be valuable for future studies of the pathogenesis and etiology of CDH.
- To analyze the possible relationship between CDH and hereditary and

environmental factors. (analogue to HAVEN-study)

Study design

Cohortstudy; data-analysis also as case-control

Study burden and risks

The burden of participants in this study will be very low. There will be no specific risks to be taken for this study. All procedures (venapuncture, amniotic puncture) all have risks of their own, but would also be performed as standard care in most cases. Mothers will undergo bloodcollection 1 or 2 times extra.
Fathers will undergo blood collection 1 time extra.
Both parents are asked to fill out questionnaires about, environmental factors as work etc. Mothers are asked to also fill out a food frequency questionnaire. The time needed to fill out these forms is about 45-60 minutes per questionanire.
This study is very important to clarify the etiology of CDH further and identify groups at risk in future. This gives us more opportunities for prevention or better (earlier) therapy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Congenital Diaphragmatic Hernia in the (unborn) child

Exclusion criteria

non-matching (controls; see protocol)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-07-2006
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	20-07-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-06-2008
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL12235.078.06