# Long term results (mortality, morbidity and quality of life) following neonatal surgical correction of esophageal atresia.

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Primary objectives1. What is the pulmonary function and exercise tolerance in children born with esophageal atresia at the age of 8-18 years (group I), determined by spirometry, measurement of lung volumes and a maximal exercise test. 2. What is the...

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Gastrointestinal tract disorders congenital |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON30122

**Source**
ToetsingOnline

**Brief title**
Long term sequellae of esophageal atresia

### Condition

- Gastrointestinal tract disorders congenital
- Gastrointestinal conditions NEC
- Gastrointestinal therapeutic procedures

**Synonym**
congenital esophageal obstruction, esophageal atresia

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

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

## Intervention

**Keyword:** esophageal atresia, gastro-esophageal reflux, long-term outcome, pulmonary function

## Outcome measures

### Primary outcome

1. Pulmonary function parameters: forced expiratory volume in 1 second (FEV1),

forced vital capacity (FVC), FEV1/FVC ratio, total lung capacity (TLC), vital

capacity (VC), residual volume (RV) and diffusion capacity (DLCO)

2. Maximal exercise test: oxygen saturation, aerobic capacity (VO2 max)

3. Increased risk of gastro-esophageal reflux, based on standardised

questionnaire

3. Health related quality of life, hased on the Child Health Questionnaire.

### Secondary outcome

none

# Study description

### Background summary

Children born with esophageal atresia may develop respiratory and gastro-intestinal complications which are well recognized during the first years of life. Approximately one third of the patients suffer from severe gastro-esophageal reflux (GER) and/or tracheamalacie.
However, variable respiratory and gastro-intestinal symptoms may continue into adolescence and adulthood. In 25-60% of the adult patients, esophagitis was demonstrated by gastroscopy. In many of these patients with GER a compatible history was lacking.
Obstructive pulmonary abnormalities have been demonstrated in 10-70% of the children born with esophageal atresia. Restrictive pulmonary abnormalities have been described in 18-36% of the patients. Lung function abnormalities may be

secondary to lung damage from recurrent and/or prolonged (micro) aspiration of gastric contents. It appears that (chronic) GER may also affect tracheamalacia.
It is unknown whether thoracotomy in the neonatal period has adverse effects on the pulmonary function.
The quality of life of children born with esophageal atresie reaching adulthood appears to be similar to the healthy population, there are no reports describing quality of life in childhood survivors of esophageal atresia.
It has been shown that children born with esophageal atresia have more learning, emotional en behavior problems than in the general population.

## Study objective

Primary objectives
1. What is the pulmonary function and exercise tolerance in children born with esophageal atresia at the age of 8-18 years (group I), determined by spirometry, measurement of lung volumes and a maximal exercise test.
2. What is the incidence of symptoms due to gastro-esophageal reflux in children born with an esophageal atresia and in children without an esophageal atresia but with a history of severe GER.
Secundary objectives
1. What is the pulmonary function and exercise tolerance in children without esophageal atresia but with a history of severe GER at the age of 8-18 years (group II), determined by spirometrie, measurement of pulmonary volumes and a maximal exercise test.
2. Could the pulmonary function abnormalities be the result of the thoracotomy performed in the neonatal period? This will be determined by comparing the pulmonary function of children born esophageal atresia and children without esophageal atresia but with a history of severe GER (group I vs group II).
3. Are there any other factors associated with pulmonary function and maximal exercise capacity, such as tracheamalacia, duration of ventilation, type of the esophageal atresia.
4. What is the quality of life of children born with esophageal atresia
5. What is the quality of life of children without esophageal atresia but with a history of severe GER.

## Study design

Observational non-invasive cohort study

## Study burden and risks

The burden for the participating patients is low. One visit to the hospital is necessary. There are no risks involved for the participants.
Currently there is no structured follow-up of these patients, hence it is likely that children with GER and pulmonary function abnormalities will be found. Children with abnormalities will be referred to the appropriate

specialist.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

### Inclusion criteria

age between 8 and 18 years
esophageal atresia OR
surgically treated gastro-esophageal reflux

### Exclusion criteria

mental retardation
prematurity (<35 wks)
recognized chronic respiratory diseases (such as cystic fibrosis)
syndromal and/or chromosomal disorders

# Study design

## Design

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-04-2006 |
| Enrollment: | 70 |
| Type: | Anticipated |

# Ethics review

Approved WMO

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| Date: | 18-05-2006 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

# 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 | NL11386.029.06 |