

# The Impact of Psychological and Medical Factors of Women having a Child with a Congenital Anatomical Malformation on Subsequent Pregnancy Decision-Making: a psychological evaluation.

Published: 26-04-2007

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To identify factors that have an influence on the reproductive decision-making for a subsequent pregnancy of women having a child with congenital anatomical anomalies.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Congenital and hereditary disorders NEC
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON30607

### Source

ToetsingOnline

### Brief title

Impact of factors on Subsequent Pregnancy Decision-Making - 1.

### Condition

- Congenital and hereditary disorders NEC
- Pregnancy, labour, delivery and postpartum conditions
- Anxiety disorders and symptoms

### Synonym

factors influencing reproductive decision-making, posttraumatic stress

### 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 anatomical malformations., decision-making., psychological evaluation, subsequent pregnancy.

## Outcome measures

### Primary outcome

Factors that influence reproductive decision-making for a subsequent pregnancy:

1. repetitive risk;
2. strength of wish for offspring;
3. prenatal testing and genetic counseling;
4. severity of the congenital anatomical malformation(s);
5. time elapsed since the birth of the afflicted child (2 or 5 years after);
6. symptoms of posttraumatic stress disorder;
7. the specific cognitive coping style (monitoring versus blunting);

### Secondary outcome

1. Anxiety, depression, somatic complaints;
2. Quality of life;
3. Adaptation.

## Study description

### Background summary

Which factors have an impact on the decision-making for a subsequent pregnancy?

- repetitive risk (10-15%, 25% or 50%)?

- strength of wish for offspring?
- prenatal testing and genetic counselling?
- severity of the malformation?
- time elapsed since the birth of the afflicted child?
- symptoms of PTSD?
- specific cognitive coping (monitoring versus blunting)?

### **Study objective**

To identify factors that have an influence on the reproductive decision-making for a subsequent pregnancy of women having a child with congenital anatomical anomalies.

### **Study design**

Retrospective design.

### **Study burden and risks**

Women will have a face-to-face semi-structured interview, which will last maximally 1,5 hours. Then a set consisting of 3 questionnaires will be given. It will take participants approximately 30 minutes to fill these in.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Dutch mothers of children with Congenital Diaphragmatic Hernia or with Esophageal Atresia, both with or without associated anomalies will be asked to participate. Their children are 2 or 5 years old at the time of inclusion.

### Exclusion criteria

1. Mothers of children diagnosed with other congenital (anatomical) anomalies than a Congenital Diaphragmatic Hernia or Esophageal Atresia,
2. Mothers of children of ages other than 2 or 5 years,
3. Mothers from other ethnic origins than the Dutch.

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-02-2008

Enrollment: 100

Type:

Actual

## Ethics review

Approved WMO

Date:

26-04-2007

Application type:

First submission

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**

CCMO

**ID**

NL13812.078.06