Posttraumatic Stress Disorder and Posttraumatic Stress Symptoms in Parents Two Years after the Diagnosis of Expecting a Child with Major Congenital Anatomical Anomalies: a prospective design regarding prevalence, course and determinants

Published: 23-01-2008
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To identify high risk groups who are in need for more and specific help and guidance, and to offer appropriate counselling.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital and hereditary disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON30791

Source
ToetsingOnline

Brief title
Impact of major congenital anatomical anomalies - 2.

Condition

- Congenital and hereditary disorders NEC
- Anxiety disorders and symptoms

Synonym
post traumatic stress disorder, traumatic 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: (symptoms of) posttraumatic stress, congenital anatomical anomalies

Outcome measures

Primary outcome

• Symptoms of PTSD.

• Symptoms of psychopathology.

Secondary outcome

1. cognitive appraisals childbirth

2. cognitive coping

Study description

Background summary

o What is the prevalence of probable PTSD and psychopathology in general two years after the diagnosis of congenital anatomical anomalies?
o Does the amount of symptoms of PTSD and of psychopathology become less in time?
o Which factors (medical, psychological, demographic) have an influence on the amount of symptoms of PTSD and on the amount of symptoms of psychopathology?

Study objective

To identify high risk groups who are in need for more and specific help and guidance, and to offer appropriate counselling.

Study design

A prospective design.

Study burden and risks

Parents will be followed from the diagnosis of congenital anatomical anomalies until two years after the birth of their child.

Inclusion will start after the prenatal diagnosis as from 20 weeks gestation OR after the postnatal diagnosis 6 weeks after the birth of the child.

Then measurements will be done 6 months, 1 year, and 2 years after the birth of the child. At each measurement parents will receive a set of 3 - 4 questionnaires; it will take approximately 30 minutes to fill these in.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Parents who are expecting a child with major congenital anatomical anomalies will be asked to participate. The anomalies are:
1.(isolated or associated) congenital diaphragmatica hernia,
2. (isolated or associated) esophageal atresia,
3. and (isolated) intestinal atresia.

Exclusion criteria

1. Parents who are expecting a child with other major congenital anomalies than a congenital diaphragmatica hernia, esophageal atresia or intestinal atresia.
2. Single parent families.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2008
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO

Date:	23-01-2008
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	ID
CCMO	NL13825.078.06