Long-term follow-up in patients with congenital anatomical malformations.

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Evaluation of long-term complaints and problems on medical, surgical, psychological, social-emotional, conditional and motoric area in patients with one or multiple congenital malformations. More knowledge on long-term morbidity will lead to better...

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

Summary

ID

NL-OMON30692

Source
ToetsingOnline

Brief title
LTFU

Condition

- Gastrointestinal tract disorders congenital
- Anal and rectal conditions NEC
- Congenital respiratory tract disorders

Synonym
anatomical birth defect, congenital anatomical malformation

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 malformation, Long-term follow-up

Outcome measures

Primary outcome

For each diagnosis assessment of :

Medical problems

Psychological functioning

Condition, motorical abilities, strenght, mobility

Quality of life, experience of illness

Social and environmental functioning (school, profession)

Secondary outcome

The amount of patients who still have complaints at the age of 18 years and

need to be transferred to the adult health care

Study description

Background summary

In the Netherlands each year 5000 children with a severe congenital, anatomical malformations are born. Congenital malformations with persistant physical handicaps and multiple hospital admissions influence a childs growth and development. Quality of life of parents and child can also be influenced. Since 2000 the physical and mental development of children with congenital malformations until the age of 12 years is monitored in a follow-up programme. Problems can be recognised at an early stage and support and/or intervention can be rapidly initialized. More and more it is being recognised that many adolescent patients still have physical and mental problems. At this age questions about inheritance can start to play a larger role. To evaluate possible problems in this group of patients, follow-up should be extended to the age of 18 years. At this age, adequate transfer to the adult health care

can be supported.

Study objective

Evaluation of long-term complaints and problems on medical, surgical, psychological, social-emotional, conditional and motoric area in patients with one or multiple congenital malformations. More knowledge on long-term morbidity will lead to better information of parents and children in the future. When a patient has complaints and/or problems, information and advise can be given and, if necessary, rapid intervention can take place.
In case of questions on inheritance, an appointment with the clinical genetic will be offered.
At the age of 18 year the patient will be adequately transferred to the adult health care.

Study design

It concerns a prospective longitudinal cohort study.

Study burden and risks

Burden:
In the current follow-up programme children at 5 and 8 years of age are tested according to an adjusted for their age, but similar schedule. The medical, psychological and motoric examination are considered to be intensive but also fun.
Most parents consider filling out the forms and a full day in the hospital as an considerable time investment. Despite this fact however, most parents are motivated to attend the full programme.

Risk:
There is no risk expected for patients and/or parents from participation in this study

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients born between 1988 and 2000 who were treated in the Sophia Children's hospital with a congenital diaphragmatic hernia, CCAML, esophageal atresia, intestinal atresia, abdominal wall defect, M. Hirschsprung, anorectal malformation and sacrococcygeal teratoma

Exclusion criteria

Lacking parental and/or patients informed consent

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):	02-01-2008
Enrollment:	700
Type:	Actual

Ethics review

Approved WMO

Date:	22-05-2007
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	ID
CCMO	NL14954.078.07