Evaluation of sexual function in adult patients with congenital anatomical anomalies of lower gastro-intestinal tract or pelvic region.

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

Summary

ID

NL-OMON38538

Source
ToetsingOnline

Brief title
Sexual function after colorectal surgery for congenital malformations.

Condition

- Congenital and hereditary disorders NEC
- Sexual function and fertility disorders

Synonym
anorectal malformation, Hirschsprung's disease, sacrococcygeal teratoma; colorectal birth 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: Anorectal malformation, Hirschsprung's disease, Sacrococcygeal teratoma, Sexual

Outcome measures

Primary outcome

The main study parameters are the outcomes of the questionnaires used as follows. For the exact content of the questionnaires we refer to section F1.

All the used questionnaires (including the quality of life questionnaire mentioned in the secondary study parameters/endpoints) are used in international studies, are validated in Dutch, and cross-culturally normed. For these questionnaires, cut-off values are available in defining what is normal and what is *sexual dysfunction*.

For female patients:

- Female sexual function index (FSFI): 19 items about sexual function.

- Female sexual distress scale (FSDS): 12 items about sexual distress.

For male patients:

- International index of erectile function (IIEF): 15 items about sexual function and distress combined.

Secondary outcome

Secondary outcome parameters are to assess the disease-specific quality of life

in these patients, and to recruit a sounding board in providing the most optimal information for future patients. This information will be obtained through the following questionnaires.

For all patients:

- Hirschsprung*s disease and Anorectal malformation Quality of Life questionnaire (HAQL):
o For patients without a stoma: 51 items about miction, defecation, and quality of life.
o For patients with a stoma: 33 items about miction and stoma function, and quality of life.
- A short self-developed questionnaire about satisfaction on the education patients received on possible sexual problems: 6 items.

Patient characteristics from responders and non-responders will be obtained from the medical records and will be compared. The results of the sexual function questionnaires of patients with a low anorectal malformation will be compared to those with a high malformation (according to the Krickenbeck classification). For Hirschsprung*s disease, the same will be done for patients with short segment vs. long segment + total aganglionosis.

Study description

Background summary

In 1999, we established a prospective long-term follow up outpatient clinic in our department for children with congenital anatomical malformations, amongst others congenital colorectal disease and sacrococcygeal teratoma. This follow-up program is now standard of care. In this program the ages and assessments at follow-up are standardized and tailor-made for the different congenital anatomical malformations. The oldest participants of this follow-up program now reach adolescent age and may become sexually active. Only a few studies are available on sexuality in (young) adults with congenital colorectal disease, with limited study samples and limited study questions. To provide optimal care and education for the current population of adolescents with colorectal malformations, more information on sexual function at older age is needed.

Study objective

The primary aim is to evaluate sexual function in adults with congenital colorectal disease and sacrococcygeal teratoma. The secondary aim of this study is to evaluate whether additional information and care on this subject has been missed and would have been necessary.

Study design

Cross-sectional study with internationally validated questionnaires on sexual function and sexual distress.

Study burden and risks

Main benefit of participating in this study is that patients may become aware that potential sexual problems could have a relationship with their congenital anatomical malformation. Adequate referral for further evaluation and treatment may be facilitated by our group. Patients will receive general information on sexual problems (a brochure of the dept. of sexology) and in addition contact names and addresses of the investigators will be given at the last questionnaire. Patients can be referred to the general practitioner or the sexologist specialized in sexual function problems in this patient group if necessary. Risks of participating in the study are minimal.

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

- Over 18 years of age at time of study, i.e. born before or in 1995.
- Anorectal malformation, Hirschsprung*s disease, or sacrococcygeal teratoma, treated in one of the participating centers.

Exclusion criteria

- Known with mental impairment (for example retrieved from medical record that the patient suffers from a syndrome with mental retardation such as Down*s syndrome), i.e. not capable of completing the questionnaires.

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):	01-12-2013
Enrollment:	0
Type:	Actual

Ethics review

Approved WMO

Date:	26-11-2013
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	NL46087.078.13