Long term effects of outflow obstruction due to congenital anomalies of the vagina, the uterus or the uterine cervix.

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Primary Objective: The painscores regarding abdominal pain among women with primary outflow obstruction in comparison with an age matched control group.Secondary Objective(s): The prevalence of sexual problems due to the congenital anomalies or the...

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

Summary

ID

NL-OMON40641

Source
ToetsingOnline

Brief title
Long term ffects of outflow obstruction.

Condition

- Congenital and hereditary disorders NEC

Synonym
Anomalies of the vagina or the uterus, obstruction of outflow

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Abdominal pain, Congenital anomalies, Menstrual obstruction, Questionnaire

Outcome measures

Primary outcome

The painscores regarding abdominal pain among women with primary outflow obstruction in comparison with an age matched control group.

Secondary outcome

The prevalence of sexual problems due to the congenital anomalies or the subsequent therapy.

The rate of women that tried to become pregnant and experienced problems regarding fertility due to the congenital anomalies or sequalae.

The use of painkillers and other therapies among women with primary outflow obstruction in comparison with an age matched control group.

Study description

Background summary

The menstrual outflow of blood can be obstructed due to congenital anomalies of the vagina, uterus or the uterine cervix. These anomalies are very low prevalent in the female population, but it results in a typically severe abdominal pain.
It is important to improve the care for girls with this anomalies, to minimalize the side effects such as long lasting pain before the first surgery, psycho-emotional harm, scar formation or organ damage.
Over the first few months of obstructed menstrual blood outflow the girls experience a progressive abdominal pain. The obstruction can cause endometriosis in the abdomen due to reversed menstrual blood into the abdominal cavity. Sensitization of the nervous system (pain hypersensitivity) may also play a role in subsequent pain problems.

Long-term studies on the effects of these problems, before and after the

primary surgery, are scarce. There is a study that describes the lessons from 30 cases of congenital anomalies of the uterine cervix (American society for Reproductive Medicine 2010 (94), Rock J., Roberts C. et al). But in this article the long term complications are not the object of study. This article also explains that the obstetric complications have not been fully reported.

To improve the care for women with the congenital anomalies as described above, it is important to investigate the long-term complications that woman report who underwent a surgical correction of the outflow canal of the vagina or the uterus. We also want to investigate whether these women experienced problems during sexual intercourse and fertility (to become pregnant or problems during their pregnancy) due to the congenital anomalies or the sequalae of the surgery. It is important to inform doctors and patients on long-term effects and complications, and therefore it is considered necessary to perform this case control study.

Study objective

Primary Objective: The painscores regarding abdominal pain among women with primary outflow obstruction in comparison with an age matched control group.

Secondary Objective(s): The prevalence of sexual problems due to the congenital anomalies or the subsequent therapy.
The rate of women that tried to become pregnant and experienced problems regarding fertility due to the congenital anomalies or sequalae.
The use of painkillers and other therapies among women with primary outflow obstruction in comparison with an age matched control group.

Study design

This is a long-term case control study among women with congenital anomalies of the vagina, the uterus or the uterine cervix who underwent a surgical correction of the menstrual outflow canal in the Radboudumc dept ob/gyn in the past 30 years. There are two surgeon*s patient lists (Wim Willemsen and Kirsten Kluivers) which are expected to be complete since 1980 and will be used for the purpose. We will send a letter, without details on the conditions studied, to ask the women whether they are willing to participate in a questionnaire study. The family doctors will be contacted to check whether addresses are still actual among women who have not been seen in the clinic for more than 5 years. After receiving patient*s agreement we will sent out a questionnaire and ask them to fill-out that list. With their answers we make an inventory of the problems they experienced after their reconstruction surgery as well as effective treatments/ strategies. They main issues of the questionnaire are on experienced abdominal pain, problems regarding sexual intercourse and fertility.
We also make a comparision to questionnaire scores and VAS-painscore in a

cohort women without obstructive anomalies. The control group will be recruited through a family doctor, who asks women of the same age as the researchgroup, without gynaecological problems, whether they want to fill-out the questionnaires for the study purpose.

Study burden and risks

This study is an inventory of the problems that women experienced in the years after the surgery of their congenital anomalies of their vagina, uterus of uterine cervix, so there are no risks associated with participation. It can be a burden to fill-out the questionnaires. We expect that women will be willing to participate.
Risk: time consumption 30 minutes.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10 Zuid -
Nijmegen 6525 GA
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10 Zuid -
Nijmegen 6525 GA
NL

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

The subjects of the group of patients meet the following requirements:
Women with congenital anomalies of the vagina, the uterus or the uterine cervix who underwent a reconstruction surgery of the menstrual outflow canal in the past.
The subjects of the control group meet the following requirements:
Women visiting the family doctor for other than gynaecological problems of the same age as the women in de patient group.

Exclusion criteria

Women will not be eligible for entry into the present study if they meet one of the following criteria:
a. Are unwilling or unable to fill-out the questionnaire.
b. The current address of the women can not be found.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-02-2015
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	02-03-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL50025.091.14