Prospective study on the treatment of congenital vaginal agenesis or vaginal hypoplasia - genital reconstruction, gynecological and urological aspects, psychosexual and social aspects and quality of life

Published: 17-01-2011
Last updated: 04-05-2024

Evaluation study on the effectiveness of a new developed vaginal dilatation programme for medical-psychological treatment of vaginal hypoplasia / agenesis.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive tract and breast disorders congenital
Study type	Interventional

Summary

ID

NL-OMON36303

Source
ToetsingOnline

Brief title
Prospective study treatment of congenital vaginal agenesis/hypoplasia

Condition

- Reproductive tract and breast disorders congenital
- Congenital reproductive tract and breast disorders
- Obstetric and gynaecological therapeutic procedures

Synonym
Disorders of sex development, hermaphroditism, intersex

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: treatment, vaginal agenesia and hypoplasia

Outcome measures

Primary outcome

Vaginal depth at the end of treatment

Capability of penile-vaginal intercourse

.

Secondary outcome

Satisfaction with sexual functioning

Study description

Background summary

Females with DSD, such as 46 XX Mayer-Rokistansky-Kuestner-Hauser syndroom, congenital adrenal hyperplasia, 46 XY and androgen insensitivity, disorders in the biosynthesis of testosterone and different types of gonadal dysgenesis have been born with vaginal hypoplasia or agenesis. In these women penile-vaginal intercourse will be impossible. For the large majority of men and women, engagements in sexual relationships contribute significantly to their quality of life. Females with DSD experience such needs too. Before entering such relationships, they need a treatment to normalise the functionality of their vagina's.
A functional vagina can be created by surgical vaginoplasty and vaginal dilatation. At present, guidelines for medical treatment have not been developed. There is consensus that psychological counselling should be offered to these women, but guidelines for psychological counselling neither have been developed. The gender team of UZ Gent and the ErasmusMC team for diagnostics

and treatment of disorders of sex development have developed a treatment existing in both medical treatment and psychological counselling.

Study objective

Evaluation study on the effectiveness of a new developed vaginal dilatation programme for medical-psychological treatment of vaginal hypoplasia / agenesis.

Study design

Prospectieve studie in women with DSD en vaginal hypoplasia/agenesis who wish to have a functional vagina. A programme of treatment have been designed including education, instruction for self dilatation, psychological counselling in the first to 4th untill the 12th months after the start of the treatment in order to optimalize success of treatment

Intervention

Enlargement of the vagina by a self dilatation procedure

Study burden and risks

The psychological interview on motivation and psychosexual development, to fill out questionnaires on (psycho)sexual functioning, self dilatation and gynecological examinations can be a psychological burden.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2060
3000 CB Rotterdam
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2060
3000 CB Rotterdam
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

Females with a disorder in sex development (DSD) and vaginal hypoplasia / aplasia
46 XY, and assigned and raised female
46, XX and assigned and raised female

Exclusion criteria

- female DSD patients who will not start vaginal dilatation therapy
- moderate to severe mental retardation (IQ below 55)
- younger than 12 years of age

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2011
Enrollment:	545
Type:	Actual

Medical products/devices used

Generic name:	vaginal dilatators
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	17-01-2011
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	NL32973.078.10