

# Outcome study on gender identity, sexual functioning and psychological well being in patients with a disorder of sexual differentiation

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In this study the prevalence and kind of sexual and psychosexual problems will be assessed. Psychological well being is studied as well

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Endocrine disorders congenital
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON35411

### Source

ToetsingOnline

### Brief title

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### Condition

- Endocrine disorders congenital
- Endocrine disorders of gonadal function
- Genitourinary tract disorders NEC

### Synonym

disorders of sexual differentiation

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** Farmaceutische industrie (Sandoz) en Stichting Pampus; 35.000 (reiskosten vergoeding patienten)

## Intervention

**Keyword:** disorder of sexual differentiation, follow-up, genital surgery, psychosexual development

## Outcome measures

### Primary outcome

1. prevalence of gender identity problems and other psychosexual problems
2. Capacity for sexual functioning
3. Satisfaction with psychosexual functioning
4. Relationship between psychopathology, acceptance of the disorder and self-esteem

### Secondary outcome

none

## Study description

### Background summary

In patients with a disorder of sexual differentiation the prenatal process of sexual differentiation did not completely follow the developmental steps into male or female. These individuals are neither completely male nor female. Having a somatosexual development that has not followed the male or female route, has large psychosocial implications. In society, in-between sex categories are not acknowledged or easily accepted. About 50 years ago guidelines for a treatment had been developed to overcome the social stigmatization and psychological problems such as confusion about one's gender identity. This treatment policy is characterized by A. assignment of gender B. endocrine and / or surgical adaptation of the body to the assigned gender. This policy had been based on the assumption of psychosexual neutrality at birth and

the dominance of social factors in the development of a person's gender identity. In the last 15 years this policy became criticized. Scientific research had shown that prenatal gonadal hormones are important in the establishment of a person's gender behavior, demonstrating that human beings are not psychosexual neutral at birth. Small studies and patients have been reported of patients who felt very unhappy in the gender they had been assigned to and raised in, some of them changed their social gender. Patient advocacy groups have put forward that the genital corrections performed in childhood seriously harm the genitalia, causing multiple sexual problems.

These data are based on case reports and a few studies in small groups of patients. These finding therefore, are unsystematic and may not be representative for the whole group of patients. They indicate however, that the present policy for treatment needs to be evaluated in a large group of patients

### **Study objective**

In this study the prevalence and kind of sexual and psychosexual problems will be assessed. Psychological well being is studied as well

### **Study design**

Patients of the divisions of pediatric endocrinology of the ErasmusMC, VUMC, UMC St. Radboud, UMC Groningen and UMC Utrecht will be asked to take part in a study on

- Evaluation of diagnosis (to assess a specific diagnosis in case this assessment have not been carried out before)
- Evaluation of genital surgery and seksual capacity
- Evaluation of gender identity problems and other psychosexual problems
- Evaluation of psychological well being

### **Study burden and risks**

not applicable

## **Contacts**

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- 1.hypervirilisation 46, XX
2. hypovirilization with 46, XY
3. gonadal dysgenesis

### Exclusion criteria

- Patients with Turner and Klinefelter syndromes - non mosaics, Mayer-Rokitansky-Kuester-Hauser syndrome
- Patients with developmental malformations of the genitourinary tract and cloacal malformations
- Moderate - severe mental retardation (IQ points below 55, DSM-IV-TR code 318)

## Study design

### Design

Study type: Observational invasive  
Intervention model: Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	13-04-2007
Enrollment:	730
Type:	Actual

## Ethics review

Approved WMO	
Date:	20-07-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO	
Date:	26-09-2007
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO	
Date:	20-12-2007
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO	
Date:	30-06-2010
Application type:	Amendment
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	NL11699.078.06