prevalence and etiological factors of testicular adrenal rest tumours in children and adolescents with congenital adrenal hyperplasia (CAH) - a multicentre study

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1. Study of the incidence of TART in male CAH children in a multicentre setting 2. Detection of predisposing factors for tumour growth. 3. Evaluating of gonadal function in male CAH children with TART

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Adrenal gland disorders
Study type	Observational non invasive

Summary

ID

NL-OMON32920

Source
ToetsingOnline

Brief title
Testicular adrenal rest tumours in pediatric CAH patients

Condition

- Adrenal gland disorders

Synonym
testicular adrenal rest tumours

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: adrenal rest tumour, congenital adrenal hyperplasia, prevalence

Outcome measures

Primary outcome

Incidence of TART during childhod and puberty

Predisposing factors for TART

Secondary outcome

Gonadal fucntion in patients with TART

Study description

Background summary

In adult male patients with congenital adrenal hyperplasia (CAH) benign testicular adrenal rest tumours (TART) is a common cause of infertility. The prevalence in the adult population is up to 94%. It is thought that the tumours consist of aberrant adrenal rests within the testes and that these tumours may already be present in childhood. The presence of TART in children is described mostly in case reports and only a limited number of studies describe its prevalence in larger populations of children and adults .

Study objective

1. Study of the incidence of TART in male CAH children in a multicentre setting
2. Detection of predisposing factors for tumour growth.
3. Evaluating of gonadal function in male CAH children with TART

Study design

Prospective, multicentre

Intervention

Ultrasonographic examination of the testes once per year.

Study burden and risks

Ultrasound is a non-invasive investigation without expected complaints for the patient. In our own centre testicular ultrasound is already used within our yearly follow up programme. Blood collection is also part of the routine programme. Early detection of TART may help to prevent tumour growth and infertility in adulthood

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Classical type of CAH

Exclusion criteria

none

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2010
Enrollment:	100
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	02-12-2009
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	NL29356.091.09