Analysis of detrusor sphincter dyssynergia in children with adolescent idiopathic scoliosis (AIS)

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The purpose of this study is to determine if the development of idiopathic scoliosis is related to neuropathic detrusor/sphincter dyssynergia. When bladder and sphincter function are disturbed, adequate therapy can be started in an early phase to...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Spinal cord and nerve root disorders
Study type	Observational non invasive

Summary

ID

NL-OMON30119

Source
ToetsingOnline

Brief title
Detrusor sphincter dyssynergia in AIS

Condition

- Spinal cord and nerve root disorders
- Bladder and bladder neck disorders (excl calculi)

Synonym
Detrusor contraction concurrent with involuntary contraction of the external urethral sphincter.

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Detrusor, dyssynergia, idiopathic scoliosis., sphincter

Outcome measures

Primary outcome

The outcome parameters of this study are:

a) normal bladder/sphincter function;

b) bladder/sphincter dysfunction (detrusor/sphincter dyssynergia).

Based upon literature, we expect that the children in our study group will show urological problems: probably 20% will have bladder/sphincter dyssynergia. In the normal paediatric population between 10 and 16 years old (= reference group), this percentage is 6%.

In our analysis, we will compare the percentage of bladder/sphincter dyssynergia in both groups by using the binomial test.

Secondary outcome

Not applicable.

Study description

Background summary

Recently, it has been hypothesized that the longitudinal growth of the spinal cord fails to keep pace with the growth of the vertebral column, and the

idiopathic scoliosis was a consequence of the maladaption of the growing immature spine to a tether created by a short spinal cord.
When this theory holds true, this abnormal stretching can cause small lesions of the spinal cord and the roots of the sacral nerves. These lesions can result in neurologic defecit, known as symptomatic tethered cord or tethered cord syndrome (TCS). The majority of patients with TCS (71%) presents with urinary incontinence as a consequence of neuropathic detrusor/sphincter dysfunction (also called detrusor/sphincter dyssynergia).

Functional tethering of the spinal cord cannot be demonstrated with magnetic resonance imaging (MRI). In daily practice, children with idiopathic scoliosis are not referred to an urologist, because in most cases there are no clear indications of urological problems. However, when this new theory holds true and functional tethering of the spinal cord plays a role in the development of idiopathic scoliosis, functioning of the bladder and external sphincter probably will be slightly disturbed, but children do not have complaints in an early phase (subclinical changes). To demonstrate subclinical changes in bladder/sphincter function additional urodynamic information is necessary.

Study objective

The purpose of this study is to determine if the development of idiopathic scoliosis is related to neuropathic detrusor/sphincter dyssynergia. When bladder and sphincter function are disturbed, adequate therapy can be started in an early phase to preserve the patient from having urological problems in the future.

Study design

Analysis of detrusor sphincter dyssynergia in children with adolescent idiopathic scoliosis (AIS) using urinary flowmetry and echography of the lower abdomen.

Study burden and risks

No significant health risks are associated with urinary flowmetry and echography of the lower abdomen.

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

Adolescent Idiopathic Scoliosis (AIS)

Exclusion criteria

No exclusion criteria.

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):	08-11-2006
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	05-09-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL12450.041.06