Cystatine-c as a marker of renal functioning in adult patients with spina bifida

Published: 27-03-2013
Last updated: 24-04-2024

To determine the value of cystatine-c based renal function assessment in adults with spina bifida when compared to the golden standard of 24-hours urine collection.

Ethical review	Not approved
Status	Will not start
Health condition type	Neurological disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON38683

Source
ToetsingOnline

Brief title
Cystatine-c in adult spina bifida patients

Condition

- Neurological disorders congenital
- Renal disorders (excl nephropathies)

Synonym
renal damage, renal impairment

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cystatine-c, renal function, spina bifida

Outcome measures

Primary outcome

Correlation coefficient of GFR as determined by cystatine-c compared to GFR

according to the golden standard.

Secondary outcome

None.

Study description

Background summary

The current method to assess renal function in spina bifida patients is serum creatinine with an estimated GFR. However, it is known that this method is not reliable in those with a reduced lean body mass, for instance because of neuromuscular disorders. Cystatine-c could be a more reliable alternative for rapid determination of renal functioning in this specific subset of patients. Besides, it is easy to determine and quite cheap when compared to the current golden standard methods (e.g. 24-hours urine collection).

Study objective

To determine the value of cystatine-c based renal function assessment in adults with spina bifida when compared to the golden standard of 24-hours urine collection.

Study design

Prospecitve, diagnostic, non-therapeutical.

Study burden and risks

There is a very small risk of urinary tract infection and irritative symptoms due to the urinary catheter.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3508 GA
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3508 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Patients with OSD (open spinal dyraphism; myelomeningocele or meningocele), or CSD (closed spinal dysraphism; all varieties of occult spina bifida including, for instance, caudal regression syndrome).
* Age > 18 years;
* Adequate cognitive functioning;
* Patient's willingness to participate;

Exclusion criteria

* Severe mental retardation;
* Hemodialyse of peritoneaaldialyse.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	49
Type:	Anticipated

Ethics review

Not approved

Date:	27-03-2013
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	NL43022.041.12