Urinary Bladder Mapping

Published: 22-05-2014
Last updated: 23-04-2024

To monitor the electric activity of the urinary bladder, and to localize the pacemaker, and the path of electric signal propagation of the detrusor muscle contractions.

Ethical review	Approved WMO
Status	Pending
Health condition type	Bladder and bladder neck disorders (excl calculi)
Study type	Observational invasive

Summary

ID

NL-OMON37931

Source
ToetsingOnline

Brief title
Urinary Bladder Mapping

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
Overactive bladder

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: Ensite, noncontact catheter, Urinary bladder

Outcome measures

Primary outcome

Detection of recordable electric activity of the urinary bladder.

Secondary outcome

To localize the pacemaker, and the path of electric signal propagation of the

detrusor muscle contraction in patients with OAB syndrome.

Study description

Background summary

Electric activity in the form of slow waves and action potentials has been recorded from the urinary bladder in humans and animals using surface EMG electrodes. The electric activity of the overactive bladder (OAB) syndrome has been shown to be dysrhythmic. The cause of the dysrhythmic pattern was ascribed to an abnormal pacemaker presumably located in the dome of the urinary bladder.

Sequential activation mapping supported by three-dimensional (3D) electroanatomic mapping systems is widely used to reconstruct the 3D spread of electrical activation throughout cardiac chamber anatomies.

Study objective

To monitor the electric activity of the urinary bladder, and to localize the pacemaker, and the path of electric signal propagation of the detrusor muscle contractions.

Study design

Feasibility study

Study burden and risks

Some mild discomfort might be experienced by the patient on introducing the catheters.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adult patients > 18 year old, with Overactive bladder symptoms.

Exclusion criteria

Patients with previous bladder surgery
Patients with urinary tract infection
Female Patients with severe genital prolapse
Pregnency

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	20-01-2014
Enrollment:	3
Type:	Anticipated

Medical products/devices used

Generic name:	Ensite Cardiac Mapping System
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	22-05-2014
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	NL46832.091.13