

# Urinary Bladder Mapping

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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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Bladder and bladder neck disorders (excl calculi)
<b>Study type</b>	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

### Public

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### Scientific

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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

Pregnancy

## 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