

# The role of GAG's in the pathology of interstitial cystitis (IC/PBS)

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Our goal is to investigate the differences in the GAG-layer of patients with normal bladders and interstitial cystitis. We also want to evaluate the role of mast cells and heparanase in the pathogenesis of interstitial cystitis.

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

## Summary

### ID

NL-OMON35118

### Source

ToetsingOnline

### Brief title

GAG-IC-study

### Condition

- Bladder and bladder neck disorders (excl calculi)

### Synonym

Interstitial cystitis, Painfull bladder syndrome

### 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:** bladder, GAG, glycosaminoglycans, interstitial cystitis, painful bladder syndrome

## Outcome measures

### Primary outcome

The bladder biopsies are used for an observational study. All material will be used to investigate the possible differences in GAG layer and mast cell in interstitial cystitis patients.

### Secondary outcome

not applicable

## Study description

### Background summary

Interstitial cystitis is a bladder disease. It causes a recurrent sterile inflammation of the bladder wall resulting in pelvic pain, urgency (an uncontrollable and uncomfortable desire to urinate) and frequency (voiding > 8x/day). The pathogenesis of this disease is still unknown, but two of the histological diagnostic features are 1) an increase of invading solutes and proteins from the urine into the bladder wall, due to an impairment of the bladder barrier and 2) an unusual colonisation of mast cells (inflammatory cells) in the bladder wall. Previous histological research (Hurst 1996, Parsons 1991) on bladder of interstitial cystitis patients detected a defect of the glycosaminoglycan (GAG) layer. The GAG-layer is part of the mucus layer of the bladder and is considered to be the first line of defence in keeping the bladder wall barrier intact. The defect that is seen in the GAG-layer of interstitial cystitis, could attribute or even be responsible for the recurrent bladder inflammation and cause the typical histological abnormalities seen in these patients. Research at our own department provided new insight on the contents of the bladder GAG-layer. Also, recent research on kidney revealed that mast cells excrete the enzyme heparanase. Heparanase is known to break down heparan sulfate, an important GAG in the human bladder. Our hypothesis is that heparanase from mast cells are responsible for the GAG-layer defects in IC.

### Study objective

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Our goal is to investigate the differences in the GAG-layer of patients with normal bladders and interstitial cystitis. We also want to evaluate the role of mast cells and heparanase in the pathogenesis of interstitial cystitis.

## **Study design**

observational study; using bladder biopsies for histological research  
(hypothesis finding study)

## **Intervention**

2 bladder biopsies per patient will be taken for research purposes (this is besides the regular diagnostic biopsies).

## **Study burden and risks**

The patients will undergo bladder biopsies. This will be done via an cystoscope, which is a device that has long tube with a small diameter, that can be inserted minimally invasive, through the urethra to gain access to the urinary bladder. The inner bladder can be visualized using camera and fiberoptics and fluid can be added or subtracted (urine) from the bladder. Also a small diameter flexible biopsy needle can be inserted through the cystoscope to take bladder wall tissue samples. These samples are always taken under local or general anaesthesia. We will only include patients that are already receiving bladder cystoscopy under general / spinal anesthesia. The risks of bladder biopsies are minimal, but it can cause : transient minor bleeding, transient minor pain and discomfort, and in rare case reports, more severe bleeding or bladder perforation has been described. Cystoscopy increases the chance of urinary infections, but this is not an added risk for patients who are already undergoing a bladder biopsy procedure.

## **Contacts**

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

All patients: age: 18-70 yrs, female, non-incapacitated

1) Patients who are undergoing bladder capacity measurements biopsies for the diagnosis of interstitial cystitis

2) Patients who are getting an operative Trans Viginal Tape placement for stress incontinenece.

### Exclusion criteria

Patients with other bladder diseases (dan interstitial cystitis). Patients with enhanced risk of bleeding (anti-thrombolitics, blood cluttering disorders etc.). incapacitated.

## Study design

### Design

|                     |                                 |
|---------------------|---------------------------------|
| Study type:         | Interventional                  |
| Intervention model: | Other                           |
| Allocation:         | Non-randomized controlled trial |
| Masking:            | Open (masking not used)         |
| Control:            | Active                          |

Primary purpose: Basic science

## Recruitment

NL  
Recruitment status: Recruiting  
Start date (anticipated): 01-09-2010  
Enrollment: 12  
Type: Actual

## Ethics review

Approved WMO  
Date: 16-02-2010  
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     | NL29890.091.09 |