

# The use of bladder instillations with hyaluronic acid in the management of young female patients with lower urinary tract symptoms and trigonitis

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<b>Registration date</b> 12/05/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/05/2021	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Trigonitis is inflammation of the trigone region of the bladder. Although trigonitis was first described more than a century ago and is a familiar term to urologists, it remains a poorly defined condition. The diagnosis is done during cystoscopy (camera inspection of the bladder) by the image of a white patch of tissue in the bladder trigone (the area between the bladder neck and the two ureteric openings). The precise underlying cause is still not well understood and its clinical significance continues to be unclear. Trigonitis has been traditionally associated with a wide range of lower urinary tract symptoms as well as with recurrent urinary tract infections. However, not all people with trigonitis have symptoms, and not all symptomatic patients have trigonitis, which complicates the understanding of this elusive disease process. The aim of this study is to find out whether the use of intravesical hyaluronic acid (treatment given directly into the bladder) in symptomatic women with trigonitis can improve their symptoms.

### Who can participate?

Young women of reproductive age with persistent lower urinary tract symptoms and evidence of trigonitis on cystoscopy

### What does the study involve?

All patients receive 10 weekly and 10 monthly treatment sessions of hyaluronic acid solution inside the bladder for a period of 1 year, which is known to repair the lining of the bladder wall. Their response to treatment is evaluated with symptom questionnaires. Each patient is assessed with a cystoscopy and biopsy (tissue sample) of trigonitis at the beginning and the end of the study.

### What are the possible benefits and risks of participating?

Benefits include potential improvement of symptoms following treatment with hyaluronic acid. Risks include potential side effects from the drug which according to previous studies are very rare. Risks also include complications from bladder instillations such as a urinary infection and

also potential complications from cystoscopy and bladder biopsy performed before and after treatment such as bladder discomfort/pain, infection and bleeding.

Where is the study run from?

National and Kapodistrian University of Athens (Greece)

When is the study starting and how long is it expected to run for?

October 2009 to April 2017

Who is funding the study?

National and Kapodistrian University of Athens (Greece)

Who is the main contact?

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## Contact information

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

The use of intravesical hyaluronic acid in the management of symptomatic premenopausal women with pseudomembranous trigonitis

### Study objectives

The use of intravesical hyaluronic acid in symptomatic women with trigonitis can improve their symptoms.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 13/11/2009, Sismanoglio Hospital Ethics Committee (Sismanogliou 1, Marousi 15126, Athens, Greece; +30 (0)2108039254; info@sismanoglio.gr), ref: 19750

### Study design

Prospective non-randomized uncontrolled study

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Treatment of lower urinary symptoms in women with trigonitis

### Interventions

Intravesical administration of 40 mg/50 ml solution of sodium hyaluronate (Cystistat) once weekly for 10 weeks and once monthly for 10 months thereafter to all patients.

### Intervention Type

Drug

### Phase

Not Applicable

**Drug/device/biological/vaccine name(s)**

Cystistat (sodium hyaluronate)

**Primary outcome(s)**

1. Pain and urgency measured using the visual analogue scale (VAS) at baseline, 10 weeks and 12 months
2. Further symptoms and quality of life measured using the Pain and Urgency/Frequency (PUF) symptom scale at baseline, 10 weeks and 12 months

**Key secondary outcome(s)**

Extent of trigonitis measured using cystoscopy and biopsy at baseline and end of treatment at 12 months

**Completion date**

02/04/2017

**Eligibility****Key inclusion criteria**

Women of reproductive age with lower urinary tract symptoms for at least 6 months and trigonitis seen on cystoscopy

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Total final enrolment**

37

**Key exclusion criteria**

1. Under 18 years
2. Pregnancy or breastfeeding
3. Radiation cystitis
4. Neurogenic bladder
5. Bladder cancer
6. Bladder stones
7. Stress incontinence
8. Urethral diverticulum
9. Pelvic organ prolapse
10. Uterine, vaginal or cervical cancers
11. Endometriosis

**Date of first enrolment**

07/01/2010

**Date of final enrolment**

04/02/2016

**Locations****Countries of recruitment**

Greece

**Study participating centre****Sismanoglio Hospital**

2nd Department of Urology

School of Medicine

University of Athens

Sismanogliou 1

Athens

Greece

151 26

**Study participating centre****Attiko Hospital**

3rd Department of Urology

School of Medicine

University of Athens

Rimini 1

Athens

Greece

124 62

**Sponsor information****Organisation**

National and Kapodistrian University of Athens

**ROR**

<https://ror.org/04gnjpp42>

**Funder(s)**

**Funder type**

University/education

**Funder Name**

National and Kapodistrian University of Athens

**Alternative Name(s)**

University of Athens

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

Greece

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

**IPD sharing plan summary**

Other