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

Submission date
17/03/2021

Recruitment status
No longer recruiting

Registration date
12/05/2021

Overall study status
Completed

Last Edited
12/05/2021

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

Type(s)
Scientific

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Additional identifiers

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

Primary study design
Interventional

Study design
Prospective non-randomized uncontrolled study

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
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151 26

Study participating centre
Attiko Hospital
3rd Department of Urology
School of Medicine
University of Athens
Rimini 1
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124 62

Sponsor information

Organisation
National and Kapodistrian University of Athens

ROR
https://ror.org/04gnjpq42

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