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Prevention of recurrent urinary tract infections by intravesical administration of hyaluronic acid and chondroitin

Submission date	Recruitment status	[_] Prospectively registered
03/11/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/03/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/02/2011	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
UROLUMG11/09

Study information

Scientific Title

Prevention of recurrent urinary tract infections by intravesical administration of hyaluronic acid and chondroitin: an interventional prospective randomised placebo-controlled trial

Study objectives
Study drug induces a 70% decrease in the rate of urinary tract infections (UTIs) per patient/year in this study population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board (IRB) of Magna Graecia University, Italy, approved on the 17th September 2009 (ref: CE/441/09)

Study design
Interventional prospective randomised double-blind placebo controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Urinary tract infections (UTIs)

Interventions
Patients will be randomised to receive:
1. Intravesical instillations of sodium HA (high molecular weight) 1.6% and CS 2.0% dose 50 ml of saline
2. Intravesical instillations of 50 ml saline (controls)

Both groups will be given therapy once weekly for 4 weeks and then once week or monthly for 5 months. Total follow-up: 12 months.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Hyaluronic acid, chondroitin

Primary outcome(s)
Rate of UTIs per patient per year. Outcome assessment at 1, 3, 6, 9 and 12 months.

Key secondary outcome(s))

Outcome assessment at 1, 3, 6, 9 and 12 months:
1. Time to UTI recurrence
2. Rate of adverse events

Completion date
31/05/2010

Eligibility

Key inclusion criteria
1. Women aged 18 - 80 years old
2. Spontaneous urination
3. Greater than three uncomplicated UTIs/previous year
4. Free from UTIs at the beginning of study
5. No ongoing prophylactic antibiotic treatment
6. Able to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Greater than 50 ml residual urine
2. Neurological bladder disease
3. Known neoplasia, urinary stone or urinary tract abnormality
4. Use of indwelling catheter
5. Renal insufficiency
6. Diabetes
7. Current corticosteroid use
8. Pregnancy
9. Immunosuppressive disease

Date of first enrolment
01/12/2009

Date of final enrolment
31/05/2010

Locations

Countries of recruitment
Italy

Study participating centre
Unità Operativa e Scuola Specializzazione in Urologia
Catanzaro
Italy
88100

Sponsor information

Organisation
Magna Graecia University (Italy)

ROR
https://ror.org/0530bdk91

Funder(s)

Funder type
University/education

Funder Name
Magna Graecia University (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes