

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

Submission date

03/11/2009

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

03/03/2010

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

02/02/2011

Condition category

Urological and Genital Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Rocco Damiano

Contact details

Unità Operativa e Scuola Specializzazione in Urologia
Università Magna Graecia di Catanzaro
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Catanzaro
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88100

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

Rate of UTIs per patient per year. Outcome assessment at 1, 3, 6, 9 and 12 months.

Secondary outcome measures

Outcome assessment at 1, 3, 6, 9 and 12 months:

1. Time to UTI recurrence
2. Rate of adverse events

Overall study start date

01/12/2009

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

60

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)

Sponsor details

Department of Urology

Policlinico Mater Domini

Germaneto

Viale Europa

Catanzaro

Italy

88100

Sponsor type

University/education

Website

<http://www.unicz.it/urologia>

ROR

Funder(s)

Funder type

University/education

Funder Name

Magna Graecia University (Italy)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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