ISRCTN37534393 https://doi.org/10.1186/ISRCTN37534393

Intravesical hyaluronic acid (HA) and chondroitin sulphate (CS) for treatment of signs and symptoms of patients with late radiation tissue cystitis (LRTC): an investigative pilot study

Submission date
05/03/2013

Recruitment status
No longer recruiting

Registration date
20/03/2013

Overall study status
Completed

Last Edited
30/06/2017

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
Radiation cystitis is a complication of radiation therapy administered to pelvic tumors. Late radiation cystitis can develop months to years after radiation therapy, and presents principally as hematuria (presence of blood in urine), which ranges from mild to life-threatening. The aim of this study is assess the tolerability, safety and effectiveness of a hyaluronic acid and chondroitin sulphate combination in patients with late radiation tissue cystitis.

Who can participate?
Patients with late radiation tissue cystitis after receiving radiotherapy for pelvic tumors

What does the study involve?
Participants are treated with a hyaluronic acid and chondroitin sulphate combination that is delivered as a liquid drug directly into the bladder through a tube (intravesical instillation). Participants with severe haematuria (daily) receive instillations 5 days/week in the 1st month, 3 days/week in the 2nd month, 2 days/week in the 3rd month, once weekly in months 4-6, every two weeks in months 7-8, every three weeks in months 9-10, and monthly/bimonthly for one year. Participants without or with occasional haematuria receive instillations 3 days/week in the 1st month, 2 days/week in the 2nd month, 1 day/week in months 3-4, every two weeks in months 5-6, every three weeks in months 7-8, and monthly/bimonthly for one year. The tolerability, safety and effectiveness of the treatment and changes in quality of life are measured at 3 and 12 months.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Vita-Salute San Raffaele University (Italy)

When is the study starting and how long is it expected to run for?
May 2010 to December 2013

Who is funding the study?
Regional Health System (Italy)

Who is the main contact?
Dr Massimo Lazzeri

Contact information

Type(s)
Scientific

Contact name
Dr Massimo Lazzeri

Contact details
Department of Urology
San Raffaele Turro
Vita-Salute San Raffaele University
Via Stamira dAncona 20
Milan
Italy
20127

Additional identifiers

Protocol serial number
001/Magenta

Study information

Scientific Title
Intravesical hyaluronic acid (HA) and chondroitin sulphate (CS) for treatment of signs and symptoms of patients with late radiation tissue cystitis (LRTC): an investigative pilot study

Study objectives
To test the hypothesis that a combined solution containing high concentration of HA and CS may improve LRTC symptoms and signs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board (001/Magenta)

Primary study design
Interventional

Study design
Prospective longitudinal non-randomized investigative pilot study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Late radiation tissue cystitis with or without haematuria

Interventions
Enrolled patients were treated with intravesical instillations of Ialuril®, a 50 ml/vial solution containing HA 800 mg and CS 1 mg. Patients with severe haematuria (daily) received instillations 5 days/week in the 1st month, 3 days/week in the 2nd month, 2 days/week in the 3rd month, once weekly in months 4-6, every two weeks in months 7-8, every three weeks in months 9-10, and monthly/bimonthly for one year.

Patients without or with occasional haematuria received instillations 3 days/week in the 1st month, 2 days/week in the 2nd month, 1 day/week in months 3-4, every two weeks in months 5-6, every three weeks in months 7-8, and monthly/bimonthly for one year. The solution was retained in the bladder for 45-60 minutes in the 1st month, with rotation in four positions (supine, prone, left and right flank), and for ≥ 80 minutes thereafter.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
The tolerability, safety and efficacy of the treatment at reducing the symptoms and signs of LRTC at 3 and 12 months

Key secondary outcome(s)
Quality of Life (QoL), measured at 3 and 12 months

Completion date
31/12/2013

Eligibility

Key inclusion criteria
Eligible patients with symptomatic LRTC after receiving primary or adjuvant radiotherapy for pelvic neoplasms

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients (male and female, age range: 40-80 years) undergoing chemotherapy
2. Those with a life expectancy of less than 24 months
3. Those with radiological confirmed metastasis
4. Patients receiving radiotherapy for bladder cancer
5. Patients with documented urethral strictures

Date of first enrolment
01/05/2010

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Italy

Study participating centre
Vita-Salute San Raffaele University
Milan
Italy
20127

Sponsor information

Organisation
Institut Biochimique SA (IBSA) (Italy)

ROR
https://ror.org/02cf8gj49

Funder(s)

Funder type
Government

Funder Name
Regional Health System (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration