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	Recruitment status	Prospectively registered
05/03/2013	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
20/03/2013	Completed	Results
Last Edited	Condition category	Individual participant data
30/06/2017	Urological and Genital Diseases	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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)

Study design

Prospective longitudinal non-randomized investigative pilot study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

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 \geq 80 minutes thereafter.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Hyaluronic acid, chondroitin sulphate

Primary outcome measure

The tolerability, safety and efficacy of the treatment at reducing the symptoms and signs of LRTC at 3 and 12 months

Secondary outcome measures

Quality of Life (QoL), measured at 3 and 12 months

Overall study start date

01/05/2010

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

Age group

Adult

Sex

Both

Target number of participants

30

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

Sponsor information

Organisation

Institut Biochimique SA (IBSA) (Italy)

Sponsor details

Via Emilia Lodi Italy 26900

Sponsor type

Industry

Website

http://www.ibsa-international.com/

ROR

https://ror.org/02cf8gj49

Funder(s)

Funder type

Government

Funder Name

Regional Health System (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