

# 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

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
05/03/2013	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
20/03/2013	Completed	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
30/06/2017	Urological and Genital Diseases	<input type="checkbox"/> 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

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## 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)

### Study design

Prospective longitudinal non-randomized investigative pilot study

## **Primary study design**

Interventional

## **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  $\geq$  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

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#"><u>Participant information sheet</u></a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes