# Intravesical Ialuril® plus oral combination of curcumine, quercetine, hyluronic acid (HA) and chondroitin sulphate (CS) for prophylaxis of recurrent non-muscle invasive transitional cell carcinoma (TCC) of the bladder

Submission date 10/03/2013	<b>Recruitment status</b> Stopped	<ul><li>Prospectively registered</li><li>Protocol</li></ul>
Registration date	Overall study status	Statistical analysis plan
20/03/2013	Stopped	☐ Results
Last Edited	Condition category	☐ Individual participant data
21/01/2019	Cancer	☐ Record updated in last year

## Plain English summary of protocol

Background and study aims

Transitional cell carcinoma (TCC) of the bladder is one of the most common cancers. In 75-85% of patients the cancer is contained inside the lining of the bladder (non-muscle-invasive bladder cancer). A surgical technique called complete transurethral resection of visible tumour (TURBT) is the gold standard treatment for non-invasive bladder tumours. A single dose of chemotherapy, usually mitomycin C, is delivered directly into the bladder using a catheter (intravesical therapy) to destroy any remaining microscopic tumour and prevent the cancer from coming back. Intravesical therapy is also used in a maintenance (long term) fashion to prolong the beneficial effects of the chemotherapy. Although immediate intravesical mitomycin C or epirubicin is highly recommended, it should not be used in patients with a bladder perforation as a small number of serious complications related to mitomycin C extravasation (leakage) have been reported. The bladder lining (urothelium) prevents undesirable substances penetrating the deeper layers of the bladder wall and neutralises toxic substances. Glycosaminoglycans (GAGs) make the inner bladder wall impervious to the contents of the urine. Two key components of the layer are hyaluronic acid (HA) and chondroitin sulphate (CS). The aim of this study is to find out whether intravesical HA and CS (Ialuril®) followed by oral HA and CS plus curcumine and quercetine are safe and effective at preventing the recurrence of TCC after TURBT.

Who can participate?
Patients aged over 18 with TCC

#### What does the study involve?

Patients receive intravesical HA and CS (Ialuril®) immediately after TURBT, followed by oral treatment with pills (one a day for 90 days) containing CS, HA, quercitine and curcumine. TCC recurrence is assessed using ultrasound, urine tests and endoscopic assessment after 3 months.

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

Where is the study run from? Institut Biochimique SA (IBSA) (Italy)

When is the study starting and how long is it expected to run for? January 2012 to December 2013

Who is funding the study? Institut Biochimique SA (IBSA) (Italy)

Who is the main contact?

Dr Massimo Lazzeri

# Contact information

## Type(s)

Scientific

#### Contact name

Dr Massimo Lazzeri

#### Contact details

via Stamira d'Ancona 20 Milan Italy 20127

# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers** 001/Ialuril Oral

# Study information

#### Scientific Title

Intravesical Ialuril® plus oral combination of curcumine, quercetine, hyluronic acid (HA) and chondroitin sulphate (CS) for prophylaxis of recurrent non-muscle invasive transitional cell carcinoma (TCC) of the bladder: a prospective longitudinal investigative pilot non-randomised study

### **Study objectives**

To test the hypothesis whether or not immediate post-TURBT intravesical instillation of a combination of HA and CS (Ialuril®) repairing coating - followed by oral administration of a combination of HA and CS plus curcumine and quercetine maintaining coating - is safe, tolerated and effective in preventing the recurrence of TCC after TURBT in patients with superficial low-intermediate risk pTa-1 TCC.

#### Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

#### Study design

Prospective longitudinal investigative pilot non-randomised (phase 1b) 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

Superficial (non muscle invasive) transitional cell carcinoma

#### **Interventions**

All the patients underwent standard transurethral resection of the visible lesions. Immediate post-TURBT intravesical instillation of a combination of HA and CS (Ialuril®: 50 ml/vial solution containing HA 800 mg and CS 1 mg) followed by oral treatment with pills (one a day for 90 days) containing CS 200 mg, HA 20 mg, quercitine 200 mg and curcumine 100 mg.

## Intervention Type

Drug

#### Phase

Phase I

# Drug/device/biological/vaccine name(s)

**Laluril®** 

#### Primary outcome measure

- 1. Tolerability, reported as discontinuation or deviation of the protocol and safety as general or local side effects
- 2. Efficacy, defined as the absence of recurrence as defined by negative ultrasound evaluation, negative urine cytology and negative endoscopic assessment after 3 months

# Secondary outcome measures

Morphological immunohistochemical assessment, comparing samples at entry and after 3 months for transient receptor protein vanilloids 1 (TRPV1) expression and GAGs

#### Overall study start date

01/01/2012

#### Completion date

31/12/2013

#### Reason abandoned (if study stopped)

Local ethical committees requested several changes

# **Eligibility**

#### Key inclusion criteria

Patients (male and female) with single, ultrasound detected < 3 cm tumor diameter, or multiple 3 or less, each < 1 cm, low- and intermediate-grade (Grade II in old nomenclature) superficial TCC at the first diagnosis, confirmed by flexible cystoscopy and cold cup biopsy

## Participant type(s)

Patient

#### Age group

Adult

#### Sex

Both

#### Target number of participants

20

#### Key exclusion criteria

- 1. Concomitant CIS
- 2. Involvement of the prostatic urethra
- 3. Neurogenic bladder
- 4. Diabetes mellitus type I and II
- 5. Previous bladder or prostate surgery (any kind)
- 6. Previous treatment with drugs (capsaicin, vanilloids, ovanil, botulinum toxin etc)
- 7. Further exclusion criteria were previous chemotherapies and/or pelvic radiotherapy

#### Date of first enrolment

01/01/2012

#### Date of final enrolment

# Locations

#### Countries of recruitment

Italy

Study participating centre via Stamira d'Ancona 20

Milan Italy 20127

# 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

Industry

#### **Funder Name**

Institut Biochimique SA (IBSA) (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