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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

Recruitment status
Stopped

Registration date
20/03/2013

Overall study status
Stopped

Last Edited
21/01/2019

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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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

31/12/2013

Locations

Countries of recruitment
Italy

Study participating centre
via Stamira d'Ancona 20
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20127

Sponsor information

Organisation
Institut Biochimique SA (IBSA) (Italy)

Sponsor details
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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