ISRCTN65811336 https://doi.org/10.1186/ISRCTN65811336

Allopurinol in the prevention of superficial bladder tumour recurrence

Submission date 01/05/2006	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 17/08/2006	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 09/01/2017	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-new-drug-help-stop-early-bladder-cancer-coming-back-after-treatment-rapor

Contact information

Type(s)
Scientific

Contact name
Mr Leyshon Griffiths

Contact details
Clinical Sciences Unit
Leicester General Hospital
Gwendolen Road
Leicester
United Kingdom
LE5 4PW
+44 (0) 116 258 4617
trlg1@le.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
06/Q2501/64

Study information

Scientific Title
Allopurinol in the prevention of superficial bladder tumour recurrence

Acronym
RAPOR

Study objectives
Allopurinol reduces the risk of recurrence of superficial bladder cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Being considered for approval by the Nottingham REC 2 (reference: UHL 9950 ETHICS 06/Q2501/64), final approval received 03/05/2006.

Study design
A single centre, randomised placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Superficial transitional cell carcinoma of the urinary bladder

Interventions
Allopurinol 100 mg once daily with food or placebo drug

Intervention Type
Drug

Phase
Phase II

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

Primary outcome measure
Time to biopsy-proven bladder tumour recurrence whilst taking allopurinol 100 mg once daily or placebo.

Secondary outcome measures
To evaluate the tolerability of allopurinol in patients with superficial bladder cancer, and to identify any adverse events.

Overall study start date
01/06/2006

Completion date
01/01/2016

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Patients with solitary Transitional Cell Carcinoma
(TCC) Ta or T1 bladder tumour (Grade one to two) that recurs at three months
2. Patients with multifocal TCC Ta bladder tumours (Grade one to two) that do not recur at three months
3. Patients with multifocal TCC Ta bladder tumours (Grade one to two) that recurs at three months

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
64 (60 at time of registration)

Key exclusion criteria
1. Tumours with a higher risk of progression to muscle-invasive bladder cancer
2. Non-TCC bladder cancer
3. Multifocal T1 or Grade three TCC
4. Carcinoma in situ
5. More than one instillation of intravesical chemotherapy
6. Intravesical Bacillus Calmette-Guerin (BCG) therapy

Other reasons:
1. Current azathioprine or mercaptopurine treatment
2. Serum creatinine more than 200 µmol/l

3. Pregnant
4. Breast feeding
5. Aged under 18 year of age
6. Previous Allopurinol hypersensitivity
7. Current allopurinol treatment

Date of first enrolment
01/06/2006

Date of final enrolment
01/01/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Sciences Unit
Leicester
United Kingdom
LE5 4PW

Sponsor information

Organisation
Leicester General Hospital (UK)

Sponsor details
Department of Research and Development
Gwendolen Road
Leicester
England
United Kingdom
LE5 4PW
+44 (0) 116 258 4199
djr8@le.ac.uk

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02zg49d29

Funder(s)

Funder type
Government

Funder Name
University Hospitals of Leicester NHS Trust (UK)

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