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Short-term administration of prulifoxacin: a preventive strategy to reduce Bacillus Calmette-Guerin (BCG)-induced toxicity in patients with superficial bladder cancer

Submission date
26/07/2008

Recruitment status
No longer recruiting

Registration date
31/07/2008

Overall study status
Completed

Last Edited
31/07/2008

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

UMG0707

Study information

Scientific Title
Antibiotic prophylaxis with 3-day course of prulifoxacin 600 mg in superficial bladder cancer patients undergoing Bacillus Calmette-Guerin (BCG) instillations: a prospective, randomised, open-label, controlled trial

Study objectives
Prulifoxacin decrease Bacillus Calmette-Guerin (BCG)-induced moderate to severe adverse events by 30%

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Magna Graecia University of Catanzaro, approved in July 2007

Study design
Single-centre, prospective, randomised, open-label, 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
BCG-induced toxicity in patients with superficial bladder cancer

Interventions
Three-day prophylactic administration of prulifoxacin (oral) 600 mg vs no prulifoxacin at each BCG intravesical instillation.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Prulifoxacin, Bacillus Calmette-Guerin (BCG)

Primary outcome measure
Adverse events classified by the investigator according to a classification grid considering duration and intensity. Total duration of follow-up: 3 months.

Secondary outcome measures
Efficacy of BCG therapy in terms of 3-month cystoscopy findings

Overall study start date
01/09/2007

Completion date
30/04/2008

Eligibility

Key inclusion criteria
1. Both males and females, age older than 18
2. Intermediate or high risk superficial bladder cancer
3. Indication for BCG intravesical adjuvant therapy after transurethral resection (TUR)
4. Signed informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
70

Key exclusion criteria
1. Patient age older than 85 years
2. World Health Organization (WHO) performance status 3 or 4
3. Previous treatment with BCG during the previous 3 months

Date of first enrolment
01/09/2007

Date of final enrolment
30/04/2008

Locations

Countries of recruitment
Italy

Study participating centre
Magna Graecia University of Catanzaro
Catanzaro
Italy
88100

Sponsor information

Organisation
Magna Graecia University of Catanzaro (UMG) (Italy)

Sponsor details
Campus Universitario di Germaneto
Catanzaro
Italy
88100

Sponsor type
University/education

Website
http://www.unicz.it

ROR
https://ror.org/0530bdk91

Funder(s)

Funder type
University/education

Funder Name
Magna Graecia University of Catanzaro (UMG) (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