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

| Submission date | Recruitment status | Prospectively registered |
|-------------------|----------------------|---|
| 26/07/2008 | No longer recruiting | Protocol |
| Registration date | Overall study status | Statistical analysis plan |
| 31/07/2008 | Completed | Results |
| Last Edited | Condition category | [] Individual participant data |
| 31/07/2008 | Cancer | Record updated in last year |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number 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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s))

Efficacy of BCG therapy in terms of 3-month cystoscopy findings

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

https://ror.org/0530bdk91

Funder(s)

Funder type

University/education

Funder Name

Magna Graecia University of Catanzaro (UMG) (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration