

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

<b>Submission date</b> 26/07/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 31/07/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 31/07/2008	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## 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