Clinical trial results:
Allopurinol in the prevention of superficial bladder tumour recurrence

Summary

EudraCT number	2005-003219-66
Trial protocol	GB
Global end of trial date	06 January 2015

Results information

Result version number	v1 (current)
This version publication date	26 February 2020
First version publication date	26 February 2020

Trial information

Trial identification

Sponsor protocol code	EDGE ID 34160

Additional study identifiers

ISRCTN number	ISRCTN65811336
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University Hospitals of Leicester NHS Trust
Sponsor organisation address	Infirmary Square, Leicester, United Kingdom, LE1 5WW
Public contact	Mr L Griffiths, University Hospitals of Leicester NHS Trust, trlg1@le.ac.uk
Scientific contact	Mr L Griffiths, University Hospitals of Leicester NHS Trust, trlg1@le.ac.uk
Sponsor organisation name	University Hospitals of Leicester NHS Trust
Sponsor organisation address	Infirmary Square. Infirmary Road, Leicester, United Kingdom, LE1 5WW
Public contact	Mr Griffiths, University Hospitals of Leicester NHS Trust, trlg1@le.ac.uk
Scientific contact	Mr Griffiths, University Hospitals of Leicester NHS Trust, trlg1@le.ac.uk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	06 January 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 January 2015
Global end of trial reached?	Yes
Global end of trial date	06 January 2015
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Patients with superficial bladder cancer, at intermediate and high risk of recurrence could benefit from an oral medication(allopurinol) used in a cancer prevention role, and thereby reduce the need for repeated hospital admissions for surgery to remove the bladder tumour (TURBT) and invasive check-up procedures(Cystoscopy). This would not only have financial benefits to the health service but also reduce patient anxiety.

Protection of trial subjects:

Ethics favourable opinion will be obtained from an appropriate committee. The Trust R&D approval is mandatory

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 September 2006
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 24
Worldwide total number of subjects	24
EEA total number of subjects	24

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	17
85 years and over	7

Subject disposition

Recruitment

Recruitment details:

The aim is to recruit 64 patients 32 to receive allopurinol and 32 to receive placebo

Randomisation procedure

The pharmacy department at Leicester General Hospital will randomise patients once allocated to Group A, B or C.

Pre-assignment

Screening details:

First superficial TCC bladder cancer diagnosis within 12 months Patients with solitary TCC Ta or T1 bladder tumour (Grade 1 or 2) that recurs at 3 months
OR Patients with multifocal TCC Ta bladder tumours (Grade 1 or 2) that do not recur at 3 months
OR Patients with multifocal TCC Ta bladder tumours (Grade 1 or 2) that recur at 3 months.

Pre-assignment period milestones

Number of subjects started	24
Number of subjects completed	24

Period 1

Period 1 title	Randomisation (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	ARM 1

Arm description:

Allopurinol

Arm type	Experimental
Investigational medicinal product name	Allopurinol (Zyloric)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

100mg tablet by oral administration daily

Arm title	Arm 2

Arm description:

Placebo

Arm type	Placebo
Investigational medicinal product name	Placebo - Lactose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
One tablet daily

Number of subjects in period 1	ARM 1	Arm 2
Started	12	12
Completed	12	12

Baseline characteristics

Reporting groups

Reporting group title	Randomisation

Reporting group description: -

Reporting group values	Randomisation	Total	
Number of subjects	24	24	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	17	17	
85 years and over	7	7	
Gender categorical Units: Subjects			
Female	7	7	
Male	17	17	

Subject analysis sets

Subject analysis set title	Recruitment
Subject analysis set type	Per protocol

Subject analysis set description:

Subjects consented that were randomised to the study

Reporting group values	Recruitment		
Number of subjects	24		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	0		
From 65-84 years	17		
85 years and over	7		

Gender categorical Units: Subjects			
Female	7		
Male	17		

End points

End points reporting groups

Reporting group title	ARM 1
Reporting group description: Allopurinol	
Reporting group title	Arm 2
Reporting group description: Placebo	
Subject analysis set title	Recruitment
Subject analysis set type	Per protocol
Subject analysis set description: Subjects consented that were randomised to the study	

Primary: Time to biopsy proven recurrence

End point title	Time to biopsy proven recurrence[1]
End point description:	
End point type	Primary
End point timeframe: 12 months	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was undertaken for this study due to insufficient recruitment

End point values	ARM 1	Arm 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[2]	0[3]		
Units: Days				
number (not applicable)				

Notes:

[2] - Insufficient numbers for analysis

[3] - insufficient numbers for analysis

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
12 months	
Adverse event reporting additional description:	
Adverse events were not collected for this study	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups	
Reporting group title	ARM 1
Reporting group description:	
Experimental	
Reporting group title	ARM 2
Reporting group description: -	

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: non serious adverse events were not collected for this study

Serious adverse events	ARM 1	ARM 2	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 12 (25.00%)	1 / 12 (8.33%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Post procedural haematuria			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Inferior ST elevated myocardia infarct Inferior STEMI			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Transurethral prostatectomy			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Reproductive system and breast disorders			
Bilateral epididymo orchitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Urinary retention			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	ARM 1	ARM 2	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported