



## Clinical trial results:

## TREATMENT OF Ta BLADDER CANCER WITH HIGH RISK OF RECURRENCE – FLUORESCENCE CYSTOSCOPY WITH OPTIMIZED ADJUVANT MITOMYCIN-C

### Summary

EudraCT number	2012-000559-15
Trial protocol	FI
Global end of trial date	01 November 2024

### Results information

Result version number	v1 (current)
This version publication date	21 December 2024
First version publication date	21 December 2024

### Trial information

#### Trial identification

Sponsor protocol code	FB2012
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#### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01675219
WHO universal trial number (UTN)	-

Notes:

### Sponsors

Sponsor organisation name	FinnBladder
Sponsor organisation address	Sairaalakatu 1, Vantaa, Finland, 05850
Public contact	FinnBladder office, FinnBladder, +358 9471 66681, aini.salo@hus.fi
Scientific contact	FinnBladder office, FinnBladder, +358 9471 66681, aini.salo@hus.fi

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:

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**Results analysis stage**

Analysis stage	Final
Date of interim/final analysis	01 November 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 November 2024
Global end of trial reached?	Yes
Global end of trial date	01 November 2024
Was the trial ended prematurely?	No

Notes:

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**General information about the trial**

Main objective of the trial:

- 1) To evaluate whether the adjuvant 6-weekly optimized MMC instillation therapy is better than single immediate postoperative instillation therapy in reducing recurrences.
- 2) To evaluate whether the PDD-guided TUR-BT is better than the conventional white light TUR-BT in reducing recurrence, which implies evaluation of whether the effect of PDD-guided TUR-BT is additive to MMC instillation therapy

Protection of trial subjects:

Every patient will be informed about the modalities in accordance with the enclosed patient information sheet. The patient is informed both in writing and verbally by the physician. The patient must have the opportunity to decide whether or not to participate in the clinical trial. The explanatory information includes the following points:

- nature of the disease
- general prognosis
- presently available diagnostic procedures
- type and aims of the clinical study
- information on the substance to be tested
- effects and side effects of therapy to be expected
- laboratory and clinical tests

to be performed

- regulations regarding confidentiality and divulgence of information
- possible review of patient data by the authorities
- storage of data
- duties of the patient (no specific duties)

Both the informing physician and the patient must sign a declaration of consent.

The patient will retain a copy of the declaration.

The declarations of consent are part of the patient file and will be retained with this.

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Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 June 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

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**Population of trial subjects****Subjects enrolled per country**

Country: Number of subjects enrolled	Finland: 510
Worldwide total number of subjects	510
EEA total number of subjects	510

Notes:

<b>Subjects enrolled per age group</b>	
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)	108
From 65 to 84 years	380
85 years and over	22

## Subject disposition

### Recruitment

Recruitment details:

Recruitment of patients was performed in Finland. Recruitment was done during the period of 13.12.2022-29.4.2022.

### Pre-assignment

Screening details:

Subjects were identified in academic urological centers and reviewed for eligibility

### Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

### Arms

Are arms mutually exclusive?	Yes
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<b>Arm title</b>	Group A
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Arm description:

Patients with TUR--BT performed under white light, followed by a single instillation of epirubicin.

Arm type	No intervention
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No investigational medicinal product assigned in this arm

<b>Arm title</b>	Group B
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Arm description:

Patients with TUR--BT performed using PDD, followed by a single instillation of epirubicin.

Arm type	Experimental
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Investigational medicinal product name	Hexvix
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Investigational medicinal product code	PR1
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Other name	
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Pharmaceutical forms	Bladder irrigation
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Routes of administration	Intravesical use
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Dosage and administration details:

85 mg milligrams intravesically

<b>Arm title</b>	Group C
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Arm description:

Patients with TUR--BT performed under white light, followed by a single instillation of epirubicin plus six optimized MMC instillations

Arm type	Experimental
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Investigational medicinal product name	Mitostat
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Investigational medicinal product code	PR2
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Other name	
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Pharmaceutical forms	Bladder irrigation
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Routes of administration	Intravesical use
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Dosage and administration details:

40 mg milligrams intravesically

<b>Arm title</b>	Group D
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Arm description:

Patients with TUR--BT performed using PDD, followed by a single instillation of epirubicin plus six optimized MMC instillations

Arm type	Experimental
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Investigational medicinal product name	Hexvix
Investigational medicinal product code	PR1
Other name	
Pharmaceutical forms	Bladder irrigation
Routes of administration	Intravesical use
Dosage and administration details: 85 mg milligrams intravesically	
Investigational medicinal product name	Mitostat
Investigational medicinal product code	PR2
Other name	
Pharmaceutical forms	Bladder irrigation
Routes of administration	Intravesical use
Dosage and administration details: 40 mg milligrams intravesically	

<b>Number of subjects in period 1</b>	Group A	Group B	Group C
Started	126	127	127
Completed	59	69	56
Not completed	67	58	71
no cancer or high grade cancer on histopathology	67	58	71

<b>Number of subjects in period 1</b>	Group D
Started	130
Completed	70
Not completed	60
no cancer or high grade cancer on histopathology	60

## Baseline characteristics

## End points

### End points reporting groups

Reporting group title	Group A
Reporting group description: Patients with TUR--BT performed under white light, followed by a single instillation of epirubicin.	
Reporting group title	Group B
Reporting group description: Patients with TUR--BT performed using PDD, followed by a single instillation of epirubicin.	
Reporting group title	Group C
Reporting group description: Patients with TUR--BT performed under white light, followed by a single instillation of epirubicin plus six optimized MMC instillations	
Reporting group title	Group D
Reporting group description: Patients with TUR--BT performed using PDD, followed by a single instillation of epirubicin plus six optimized MMC instillations	

### Primary: Bladder cancer recurrence

End point title	Bladder cancer recurrence <sup>[1]</sup>
End point description:	
End point type	Primary
End point timeframe: Analysis of time to From randomisation to recurrence or to last follow-up date.	
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: Preparing final publication and data available after publication	

End point values	Group A	Group B	Group C	Group D
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	69	56	70
Units: occurrence of biopsy confirmed Ta--1 tu	7	13	11	7

### Statistical analyses

No statistical analyses for this end point

## Adverse events

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### Adverse events information<sup>[1]</sup>

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Timeframe for reporting adverse events:

Overall trial 13.12.2012-1.11.2024

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Adverse event reporting additional description:

As this was academic, investigator initiated trial investigating authorised products in routine clinical use, no formal monitoring was carried out

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Assessment type	Non-systematic
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### Dictionary used

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Dictionary name	MedDRA
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Dictionary version	2.1
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Frequency threshold for reporting non-serious adverse events: 5 %

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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: Preparing final publication and data available after publication



## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported

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### Online references

<http://www.ncbi.nlm.nih.gov/pubmed/31177305>

<http://www.ncbi.nlm.nih.gov/pubmed/35094962>