



Clinical trial results:

Neoadjuvant short-term Intensive Chemoresection versus Standard Adjuvant intravesical instillations in NMIBC

- A study on effect and tolerability of neoadjuvant short-term intensive chemoresection and molecular markers for prediction of chemo-response

Summary

EudraCT number	2017-001189-98
Trial protocol	DK
Global end of trial date	01 November 2024

Results information

Result version number	v1 (current)
This version publication date	04 January 2026
First version publication date	04 January 2026
Summary attachment (see zip file)	NICSA summary (NICSA summary.pdf)

Trial information

Trial identification

Sponsor protocol code	NICSA
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03348969
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Aarhus University Hospital
Sponsor organisation address	Palle Juul-Jensens Boulevard 82, Aarhus N, Denmark, 8200
Public contact	Jørgen Bjerggaard Jensen, Aarhus Universitets Hospital, 0045 78452617, Bjerggaard@skejby.rm.dk
Scientific contact	Jørgen Bjerggaard Jensen, Aarhus Universitets Hospital, 0045 78452617, Bjerggaard@skejby.rm.dk

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	10 June 2024
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	01 November 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim of the study is to assess the efficacy of a neoadjuvant, short-term, intensive intravesical chemoresection with Mitomycin C compared to standard treatment with TURB and adjuvant intravesical instillation therapy.

We hypothesize that the chemoresection induced in the short-term, intensive intravesical instillation with Mitomycin C will result in a permanent low recurrence rate in patients with NMIBC, not significantly different from patients treated with TURB and standard adjuvant instillation therapy.

We also hypothesize that a reduction in number of TURBs will be seen in the intervention group based on avoidance of TURBs in patients with complete chemoresection by the short-term, intensive intravesical instillations.

Protection of trial subjects:

Not applicable

Background therapy:

Not applicable

Evidence for comparator:

Not applicable

Actual start date of recruitment	01 October 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 120
Worldwide total number of subjects	120
EEA total number of subjects	120

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)	1
From 65 to 84 years	96
85 years and over	23

Subject disposition

Recruitment

Recruitment details:

120 participants were enrolled in the study. 1 participant withdrew from the study prior to commencing study related activities or treatment.

Pre-assignment

Screening details:

357 potential candidates were screened for participation. Participants with a history of Ta low- or high-grade NMIBC were candidates for the study upon recurrence.

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
Arm title	Chemoablation

Arm description:

The intervention group received intravesical MMC (40 mg/40 mL) three times a week for 2 weeks and TURBT or office biopsy only if the response was incomplete.

Arm type	Experimental
Investigational medicinal product name	Mitomycin C Medac
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Intravesical solution
Routes of administration	Intravesical use

Dosage and administration details:

40 mg/40 mL mitomycin C, intravesically three times per week for 2 weeks

Arm title	Control
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Arm description:

The control group received TURBT or office biopsy and 6 weekly adjuvant instillations.

Arm type	Standard of care
Investigational medicinal product name	Mitomycin C Medac
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Intravesical solution
Routes of administration	Intravesical use

Dosage and administration details:

40 mg/40 mL mitomycin C, intravesically once per week for 6 weeks

Number of subjects in period 1	Chemoablation	Control
Started	59	61
End of recruitment	59	61
Completed	56	52
Not completed	3	9
Consent withdrawn by subject	1	-
benign pathology	-	2
patient refusal	-	4
comorbidities	-	1
side effects	2	2

Baseline characteristics

Reporting groups

Reporting group title	Overall trial
Reporting group description: -	

Reporting group values	Overall trial	Total	
Number of subjects	120	120	
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)	1	1	
From 65-84 years	96	96	
85 years and over	23	23	
Age continuous			
control group: 70(65-76) Chemoablation group: 72(66-77)			
Units: years			
median	71		
inter-quartile range (Q1-Q3)	65 to 77	-	
Gender categorical			
Units: Subjects			
Female	34	34	
Male	86	86	
Number of Tumours at inclusion			
Units: Subjects			
2-7	98	98	
>8	22	22	
Tumour size, mm			
Units: Subjects			
<5	55	55	
6-10	35	35	
11-20	19	19	
21-30	5	5	
>30	2	2	
not specified	4	4	
Previous BCG treatment			
Units: Subjects			
Yes	13	13	
No	107	107	
Histology before inclusion			
Units: Subjects			
Low Grade	85	85	

High Hrade	35	35	
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End points

End points reporting groups

Reporting group title	Chemoablation
Reporting group description: The intervention group received intravesical MMC (40 mg/40 mL) three times a week for 2 weeks and TURBT or office biopsy only if the response was incomplete.	
Reporting group title	Control
Reporting group description: The control group received TURBT or office biopsy and 6 weekly adjuvant instillations.	

Primary: Procedures

End point title	Procedures
End point description:	
End point type	Primary
End point timeframe: 5-year follow-up period	

End point values	Chemoablation	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	61		
Units: procedures				
number (not applicable)				
Procedures	10	0		
TURBT	37	54		

Statistical analyses

Statistical analysis title	Chi-squared
Statistical analysis description: procedure rates	
Comparison groups	Chemoablation v Control
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	≤ 0.05
Method	Chi-squared

Secondary: 5 year recurrence free survival

End point title	5 year recurrence free survival
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End point description:

5 year Recurrence free survival (RFS)

End point type	Secondary
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End point timeframe:

5 years

End point values	Chemoablation	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	59	61		
Units: patients				
number (confidence interval 95%)				
5 year RFS	14 (7 to 27)	28 (18 to 42)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All participants of the study, who receive intravesical treatment with Mitomycin C, will be interviewed in order to describe side effects and adverse events associated with the treatment. Interviews will be conducted using templates from the national

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	21.1
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Reporting groups

Reporting group title	overall
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Reporting group description: -

Serious adverse events	overall		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 119 (0.00%)		
number of deaths (all causes)	13		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	overall		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	60 / 119 (50.42%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Dysuria			
subjects affected / exposed	47 / 119 (39.50%)		
occurrences (all)	47		
Pollakiuria			
subjects affected / exposed	60 / 119 (50.42%)		
occurrences (all)	60		
Palmar erythema			
subjects affected / exposed	12 / 119 (10.08%)		
occurrences (all)	12		
Cystitis			

subjects affected / exposed	8 / 119 (6.72%)		
occurrences (all)	8		
Haematuria			
subjects affected / exposed	18 / 119 (15.13%)		
occurrences (all)	18		
Incontinence			
subjects affected / exposed	25 / 119 (21.01%)		
occurrences (all)	25		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 May 2020	amendment approved for additional analysis methods
04 January 2021	change of follow-up to follow national standards

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Relatively small sample size, few HG tumors, and RFS assessed as a secondary endpoint with unblinded cystoscopy, short MMC chemoresection without maintenance and inclusion of fulgurations without biopsy.

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/32736928>

<http://www.ncbi.nlm.nih.gov/pubmed/36223555>