



Clinical trial results:

Efficacy of immunotherapy in patients with MMR-deficient localized colon cancer scheduled for curative surgery - A prospective, phase II study

Summary

EudraCT number	2021-006046-12
Trial protocol	DK
Global end of trial date	06 June 2024

Results information

Result version number	v1 (current)
This version publication date	13 August 2025
First version publication date	13 August 2025

Trial information

Trial identification

Sponsor protocol code	05011121
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05662527
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Rigshospitalet
Sponsor organisation address	Blegdamsvej 9, Copenhagen, Denmark, 2100
Public contact	Camilla Qvortrup, Rigshospitalet, +45 35455909, camilla.qvortrup@regionh.dk
Scientific contact	Camilla Qvortrup, Rigshospitalet, +45 35455909, camilla.qvortrup@regionh.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	18 June 2025
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	06 June 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study is to evaluate the efficacy of neoadjuvant treatment with pembrolizumab before colonic resection in patients with early-stage (I-III) dMMR colon cancer.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 April 2022
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	Denmark: 85
Worldwide total number of subjects	85
EEA total number of subjects	85

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)	14
From 65 to 84 years	68
85 years and over	3

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Between February 17th, 2023 and March 1st, 2024 a total of 117 patients were assessed for eligibility in the study

Period 1

Period 1 title	Actual start of recruitment (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Pembrolizumab
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for concentrate and solution for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

4mg/kg (maximum 400mg) intravenous infusion administered over 30 min.

Number of subjects in period 1	Pembrolizumab
Started	85
Completed	85

Baseline characteristics

Reporting groups

Reporting group title	Actual start of recruitment
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Reporting group description: -

Reporting group values	Actual start of recruitment	Total	
Number of subjects	85	85	
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)	14	14	
From 65-84 years	68	68	
85 years and over	3	3	
Gender categorical Units: Subjects			
Female	61	61	
Male	24	24	

End points

End points reporting groups

Reporting group title	Pembrolizumab
Reporting group description: -	

Primary: Pathological complete response

End point title	Pathological complete response ^[1]
End point description:	

End point type	Primary
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End point timeframe:

At time of surgery

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: It is a single arm thus non-comperative study therefore not no statistical analyses have been added

End point values	Pembrolizumab			
Subject group type	Reporting group			
Number of subjects analysed	84 ^[2]			
Units: Rate	37			

Notes:

[2] - One patient did not undergo surgery

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Until 4 weeks after surgery

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCAE
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Dictionary version	5
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Reporting groups

Reporting group title	Pembrolizumab
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Reporting group description: -

Serious adverse events	Pembrolizumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 85 (5.88%)		
number of deaths (all causes)	2		
number of deaths resulting from adverse events	0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 85 (1.18%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
hepatitis			
subjects affected / exposed	1 / 85 (1.18%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	1 / 85 (1.18%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Adrenal insufficiency			
subjects affected / exposed	1 / 85 (1.18%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Myositis			

subjects affected / exposed	1 / 85 (1.18%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Pembrolizumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	70 / 85 (82.35%)		
Investigations			
alan			
subjects affected / exposed	4 / 85 (4.71%)		
occurrences (all)	4		
Anaemia			
subjects affected / exposed	19 / 85 (22.35%)		
occurrences (all)	19		
Weight decreased			
subjects affected / exposed	7 / 85 (8.24%)		
occurrences (all)	7		
Nervous system disorders			
Headache			
subjects affected / exposed	5 / 85 (5.88%)		
occurrences (all)	5		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	32 / 85 (37.65%)		
occurrences (all)	32		
Immune system disorders			
Hyperthyroidism			
subjects affected / exposed	7 / 85 (8.24%)		
occurrences (all)	7		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	15 / 85 (17.65%)		
occurrences (all)	15		
Constipation			

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>4 / 85 (4.71%)</p> <p>4</p>			
<p>Appetite disorder</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>13 / 85 (15.29%)</p> <p>13</p>			
<p>Respiratory, thoracic and mediastinal disorders</p> <p>Dyspnoea</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>10 / 85 (11.76%)</p> <p>10</p> <p>Pneumonia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>4 / 85 (4.71%)</p> <p>4</p>			
<p>Skin and subcutaneous tissue disorders</p> <p>Pruritus</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>6 / 85 (7.06%)</p> <p>6</p> <p>Rash</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>7 / 85 (8.24%)</p> <p>7</p>			
<p>Musculoskeletal and connective tissue disorders</p> <p>Arthralgia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>7 / 85 (8.24%)</p> <p>7</p> <p>Myalgia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>4 / 85 (4.71%)</p> <p>4</p>			

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 September 2023	addition of secondary endpoints Change in the expected end date of study

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.

Non randomized

Notes:

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/39692004>