



Clinical trial results:

Neoadjuvant CHEmoradiotherapy with sequential Ipilimumab and Nivolumab in RECTal cancer (CHINOREC): a prospective randomized, open-label, multicenter, phase II clinical trial

Summary

EudraCT number	2019-003865-17
Trial protocol	AT
Global end of trial date	15 March 2024

Results information

Result version number	v1 (current)
This version publication date	28 July 2025
First version publication date	28 July 2025

Trial information

Trial identification

Sponsor protocol code	CA209-7HJ
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04124601
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Waehringer Guertel 18-20, Vienna, Austria, 1090
Public contact	Organizational unit leader, Medical University of Vienna, viszeralchirurgie@meduniwien.ac.at
Scientific contact	Organizational unit leader, Medical University of Vienna, viszeralchirurgie@meduniwien.ac.at

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	15 March 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 March 2024
Global end of trial reached?	Yes
Global end of trial date	15 March 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Safety, tolerability and feasibility of standard neoadjuvant CRT with sequential ipilimumab and nivolumab following surgical resection.

Protection of trial subjects:

The trial was conducted in accordance with the Declaration of Helsinki, ICH GCP guidelines, and all applicable regulatory requirements. Written informed consent was obtained from all participants prior to any study procedures. Ethics Committee and regulatory approvals were obtained before trial initiation. Participant confidentiality was maintained in compliance with data protection laws, and safety was monitored throughout the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 January 2020
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	Austria: 80
Worldwide total number of subjects	80
EEA total number of subjects	80

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)	50
From 65 to 84 years	30
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Screening investigations will be done according to standard routine surgical practice for patients with rectal cancer who need a neoadjuvant CR.

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	Treatment

Arm description:

Experimental: Neoadjuvant Chemoradiotherapy, Ipilimumab, Nivolumab

Neoadjuvant Chemoradiotherapy (50 Gy in 2 Gy fractions + Capecitabine 1650 mg/m²/d over 25 working days) with sequential Ipilimumab (1 mg/kg IV on day 7) and Nivolumab (3 mg/kg IV on day 14, 28 and 42)

Arm type	Experimental
Investigational medicinal product name	Ipilimumab and Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Infusion

Dosage and administration details:

Experimental: Neoadjuvant Chemoradiotherapy, Ipilimumab, Nivolumab

Neoadjuvant Chemoradiotherapy (50 Gy in 2 Gy fractions + Capecitabine 1650 mg/m²/d over 25 working days) with sequential Ipilimumab (1 mg/kg IV on day 7) and Nivolumab (3 mg/kg IV on day 14, 28 and 42)

Arm title	Control
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Arm description:

Other: Neoadjuvant Chemoradiotherapy

Neoadjuvant Chemoradiotherapy (50 Gy in 2 Gy fractions + Capecitabine 1650 mg/m²/d over 25 working days)

Arm type	Active comparator
Investigational medicinal product name	Capecitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

Other: Neoadjuvant Chemoradiotherapy

Neoadjuvant Chemoradiotherapy (50 Gy in 2 Gy fractions + Capecitabine 1650 mg/m²/d over 25 working days)

Number of subjects in period 1	Treatment	Control
Started	50	30
Completed	50	30

Baseline characteristics

End points

End points reporting groups

Reporting group title	Treatment
Reporting group description: Experimental: Neoadjuvant Chemoradiotherapy, Ipilimumab, Nivolumab Neoadjuvant Chemoradiotherapy (50 Gy in 2 Gy fractions + Capecitabine 1650 mg/m2/d over 25 working days) with sequential Ipilimumab (1 mg/kg IV on day 7) and Nivolumab (3 mg/kg IV on day 14, 28 and 42)	
Reporting group title	Control
Reporting group description: Other: Neoadjuvant Chemoradiotherapy Neoadjuvant Chemoradiotherapy (50 Gy in 2 Gy fractions + Capecitabine 1650 mg/m2/d over 25 working days)	
Subject analysis set title	Analysis sets
Subject analysis set type	Safety analysis
Subject analysis set description: Treatment set This analysis set includes all subjects who were randomized to the treatment arm and received neoadjuvant CRT with sequential Ipilimumab and Nivolumab and did not violate the protocol in a way that might affect the evaluation of the effect of the study drugs on the primary objective. Control set This analysis set includes all subjects who were randomized to the control arm and received neoadjuvant CRT and did not violate the protocol in a way that might affect the evaluation of the effect of the study drugs on the primary objective.	

Primary: Primary Outcome

End point title	Primary Outcome
End point description: Incidence of treatment-emergent adverse events will be assessed according to the latest "Clavien- Dindo Classification of surgical complications" and Common Terminology Criteria of Adverse Events (CTCAE).	
End point type	Primary
End point timeframe: 20 weeks	

End point values	Treatment	Control	Analysis sets	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	50	30	80	
Units: 1-5				
number (not applicable)	50	30	80	

Statistical analyses

Statistical analysis title	Primary endpoint analysis
Statistical analysis description: Safety and tolerability will be assessed by comparing case numbers for any complication in the treatment arm (n=50) with the calculated 95% upper CI numbers of the calculated percentage of expected numbers of current standard therapy (Table 2). Case numbers in the control arm (n=30) will be used to validate expected numbers from current standard therapy (i.e. will be compared to the	

corresponding 95% CI lower and upper borders).

Comparison groups	Control v Treatment
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.05 ^[1]
Method	Exact binomial test

Notes:

[1] - Safety and tolerability will be assessed by comparing case numbers for any complication in the treatment arm (n=50) with the calculated 95% upper CI numbers of the calculated percentage of expected numbers of current standard therapy (Table 2).

Adverse events

Adverse events information

Timeframe for reporting adverse events:

20 weeks

Adverse event reporting additional description:

The study duration for the individual participant will be approximately 20 weeks: 5 weeks of standard neoadjuvant CRT, following surgery 10 to 12 weeks after, including routine clinical and diagnostic work up of about 3 weeks.

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCAE
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Dictionary version	5.0
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Reporting groups

Reporting group title	Myositis
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Reporting group description: -

Serious adverse events	Myositis		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 50 (6.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Musculoskeletal and connective tissue disorders			
Myositis			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences causally related to treatment / all	6 / 6		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Myositis		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 50 (6.00%)		
Musculoskeletal and connective tissue disorders			
Myositis			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	3		

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