Clinical trial results:
Postoperative adjuvant radiochemotherapy (aRCH) with Cisplatin (C) versus aRCH with C and Pembrolizumab (P) in locally advanced head and neck squamous cell carcinoma (HNSCC); multicenter randomized Phase II study within the German interdisciplinary study group of German Cancer Society (IAG KHT); Pembro-Adjuvant-highRisk

Summary

EudraCT number	2017-002546-74
Trial protocol	DE
Global end of trial date	30 January 2025

Results information

Result version number	v1 (current)
This version publication date	01 May 2026
First version publication date	01 May 2026
Summary attachment (see zip file)	ADRISK_Ergebnisbericht_final_2026-01-19_publish (ADRISK_Ergebnisbericht_final_2026-01-19_publish.pdf)

Trial information

Trial identification

Sponsor protocol code	ADRISK

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03480672
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Leipzig University
Sponsor organisation address	Ritterstr. 26, Leipzig, Germany,
Public contact	Anett Schmiedeknecht, Leipzig University, andreas.dietz@medizin.uni-leipzig.de
Scientific contact	Andreas Dietz, Leipzig University, andreas.dietz@medizin.uni-leipzig.de

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	23 July 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 January 2025
Global end of trial reached?	Yes
Global end of trial date	30 January 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To show that addition of Pembrolizumab (P) to postoperative adjuvant radiochemotherapy (aRCH) with Cisplatin (C) improves event free survival (EFS) compared with aRCH alone in locally advanced intermediate and high risk head and neck squamous cell carcinoma (HNSCC)

Protection of trial subjects:

not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 August 2018
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	Germany: 211
Worldwide total number of subjects	211
EEA total number of subjects	211

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)	144
From 65 to 84 years	67
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

From 2018-08-06 to 2023-11-30 a total of 220 patients were registered to the trial, from which 211 were randomised.

Pre-assignment

Screening details:

From 2018-08-06 to 2023-11-30 a total of 220 patients were registered to the trial, from which 211 were randomised.

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	PaRCH

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	Keytruda
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

200 mg per infusion, in 3-week cycle, applied in maximally 18 cyles within the 1st year of trial

in combination with standard radiochemotherapy (aRCH) - see Arm 2

Arm title	aRCH

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	aRCH
Investigational medicinal product code	
Other name	Cisplatin, Carboplatin, Radiotherapy
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

- standard treatment (adjuvant radio-chemotherapy):

Radiotherapy: standard adjuvant radiotherapy (e.g., pN0 50 Gy; pN1 56 Gy; pECS + primary 66 Gy)
Chemotherapy: (according to the respective standard of the trial site)

- Cisplatin cumulative dose 300 mg/m2 body surface according to Cooper/Bernier (Cooper et al. 2004; Bernier et al. 2004),

or

- Cisplatin cumulative dose: 280 mg/m2 body surface, e.g., Cisplatin 40 mg/m2 iv, weekly in 1-7th week of treatment

In the case of a cisplatin intolerance (e.g., resulting in relevantly impaired function of kidneys) during aRCH, it was possible to switch to carboplatin

Number of subjects in period 1[1]	PaRCH	aRCH
Started	102	102
Completed	102	102

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: In FAS only patients considered who started treatment according to trial protocol.

Baseline characteristics

Reporting groups	
Reporting group title	PaRCH
Reporting group description: -	
Reporting group title	aRCH
Reporting group description: -	

Reporting group values	PaRCH	aRCH	Total
Number of subjects	102	102	204
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			0
85 years and over			0
Age continuous Units: years			
arithmetic mean	60.6	59.8	
standard deviation	± 8.4	± 8.6	-
Gender categorical Units: Subjects			
Female	21	17	38
Male	81	85	166

Subject analysis sets	
Subject analysis set title	FAS
Subject analysis set type	Full analysis
Subject analysis set description: only patients with treatment considered according to clinical trial protocol	

Reporting group values	FAS		
Number of subjects	204		
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			

Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years arithmetic mean standard deviation	 60.2 ± 8.5		
Gender categorical Units: Subjects			
Female Male	38 166		

End points

End points reporting groups	
Reporting group title	PaRCH
Reporting group description: -	
Reporting group title	aRCH
Reporting group description: -	
Subject analysis set title	FAS
Subject analysis set type	Full analysis
Subject analysis set description: only patients with treatment considered according to clinical trial protocol	

Primary: Event Free Survival (EFS)	
End point title	Event Free Survival (EFS)
End point description:	
End point type	Primary
End point timeframe: EFS - time from randomization to the first event, i.e.: locoregional or distant recurrence occurrence of further malignoma death from any cause, or initiation of a new anti-cancer treatment without a previous EP-event	

End point values	PaRCH	aRCH		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102	102		
Units: month				
number (confidence interval 95%)	69.4 (60.3 to 79.9)	64.8 (55.7 to 75.5)		

Statistical analyses

Statistical analysis title	Confirmatory analysis
Statistical analysis description: Cox regression	
Comparison groups	PaRCH v aRCH
Number of subjects included in analysis	204
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.423
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.812

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.487
upper limit	1.353

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

From time of first intervention (day 1) until 90 days following cessation of pembrolizumab treatment, or up to initiation of a new anti-cancer treatment whichever is earlier. In control arm documentation must be to month 3 (1st efficacy Follow-up).

Adverse event reporting additional description:

Details - see attached final trial report: ADRISK_Ergebnisbericht_final_2026-01-19_publish

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.1

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

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: Details - see attached final trial report: ADRISK_Ergebnisbericht_final_2026-01-19_publish

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 February 2019	Changes in patient informed consent (e.g., new side effects and changes in the frequency of side effects) and minor changes at trial protocol --> according to the sponsor's assessment without relevance for safety or efficacy
12 July 2019	Changes in patient informed consent (e.g., new side effects and changes in the frequency of side effects) and minor changes at trial protocol --> according to the sponsor's assessment without relevance for safety or efficacy
14 October 2020	Changes in patient informed consent (e.g., new side effects and changes in the frequency of side effects; change to data protection section due to new requirements) and minor changes in the trial protocol (e.g., prolongation of the recruitment time; more detailed explanation of time lines in visit schedule) --> according to the sponsor's assessment without relevance for safety or efficacy
27 May 2021	Changes in patient informed consent (e.g., new side effects and changes in the frequency of side effects) and minor changes at trial protocol (e.g., clearer definition of the starting of reporting period/obligation of AE/SAE; primary endpoint events were specified on the basis of the experience gained during the course of the trial) --> according to the sponsor's assessment without relevance for safety or efficacy
09 June 2022	Changes in trial protocol: Prolongation of recruitment time
10 July 2023	Changes in patient informed consent (e.g., new side effects and changes in the frequency of side effects) and changes at trial protocol (e.g., a shortened follow-up period for the last patients due to premature end of the trial) --> according to the sponsor's assessment without relevance for safety or efficacy

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported