



Clinical trial results: Endoscopic electrochemotherapy in esophageal cancer – a phase II clinical trial

Summary

EudraCT number	2020-002878-27
Trial protocol	DK
Global end of trial date	23 June 2023

Results information

Result version number	v1 (current)
This version publication date	27 November 2023
First version publication date	27 November 2023
Summary attachment (see zip file)	Published paper (ECTvsAPC paper.pdf)

Trial information

Trial identification

Sponsor protocol code	EECT2020
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Michael Achiam
Sponsor organisation address	Blegdamsvej 9, Copenhagen, Denmark, 2100
Public contact	Charlotte Egeland , Charlotte Egeland , +45 20855881, charlotte.karin.linnea.egeland.02@regionh.dk
Scientific contact	Charlotte Egeland , Charlotte Egeland , +45 20855881, charlotte.karin.linnea.egeland.02@regionh.dk
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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	01 July 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 June 2023
Global end of trial reached?	Yes
Global end of trial date	23 June 2023
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Investigating if a single treatment with electrochemotherapy debulks an esophageal tumors, thereby facilitating the patients' ability to eat and drink, and also prolongs the interval before definitive stenting is required. Further investigate whether the effect lasts longer than the effect from argon plasma coagulation.

Protection of trial subjects:

n/a

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 2021
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: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

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)	5
From 65 to 84 years	5

85 years and over	0
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Subject disposition

Recruitment

Recruitment details:

Patients with newly diagnosed esophageal cancer, not candidates for potentially curative treatment, could be enrolled in the trial.

Pre-assignment

Screening details:

All patients referred to the hospital with non-curable esophageal cancer were screened for inclusion.

Period 1

Period 1 title	Over all 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	Electrochemtherapy

Arm description:

Electrochemtherapy with bleomycin

Arm type	Experimental
Investigational medicinal product name	Bleomycin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous bolus use

Dosage and administration details:

Bleomycin, Baxter A/S

15.000 IU/m2 body surface area

Arm title	Argon Plasma Coagulation
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Arm description:

Argon Plasma Coagulation

Arm type	Intervention, no drug
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	Electrochemtherapy	Argon Plasma Coagulation
Started	5	5
Completed	5	4
Not completed	0	1
Consent withdrawn by subject	-	1

Baseline characteristics

End points

End points reporting groups

Reporting group title	Electrochemotherapy
Reporting group description: Electrochemotherapy with bleomycin	
Reporting group title	Argon Plasma Coagulation
Reporting group description: Argon Plasma Coagulation	

Primary: Interventional Treatment Demanding Dysphgia

End point title	Interventional Treatment Demanding Dysphgia ^[1]
End point description:	

End point type	Primary
End point timeframe: Remaining lifetime or at least 1 year.	

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: No statistical comparisons were made due to the low patient number.

End point values	Electrochemotherapy	Argon Plasma Coagulation		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	4		
Units: 2	0	2		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

14 days after treatment

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	Electrochemtherapy
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Reporting group description:

Electrochemtherapy with bleomycin

Reporting group title	Argon Plasma Coagulation
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Reporting group description:

Argon Plasma Coagulation

Serious adverse events	Electrochemtherapy	Argon Plasma Coagulation	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	
number of deaths (all causes)	2	3	
number of deaths resulting from adverse events	0	0	
Renal and urinary disorders			
Dehydration/hyperkalemia	Additional description: One patient was re-admitted shortly after treatment with ECT due to dehydration and hyperkalemia.		
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Electrochemtherapy	Argon Plasma Coagulation	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 5 (60.00%)	1 / 4 (25.00%)	
General disorders and administration site conditions			
Syncope			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Gastrointestinal disorders			

Dysphagia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Nausea			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Pain			
subjects affected / exposed	2 / 5 (40.00%)	0 / 4 (0.00%)	
occurrences (all)	2	0	

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