Clinical trial results:
Endoscopic assisted Calcium electroporation in esophageal cancer – a safety study

Summary

EudraCT number	2020-005787-58
Trial protocol	DK
Global end of trial date	04 July 2022

Results information

Result version number	v1 (current)
This version publication date	05 October 2023
First version publication date	05 October 2023
Summary attachment (see zip file)	Published manuscript (Cancers_paper_CaEP.pdf)

Trial information

Trial identification

Sponsor protocol code	eCaEP2021

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
Sponsor organisation name	Michael Achiam
Sponsor organisation address	Blegdamsvej 9, Copenhagen, Denmark, 2100
Public contact	Michael Achiam, Dept. of Surgery and Transplantation, Rigshospitalet, Copenhagen University Hospital, +45 34450441, michael.patrick.achiam.01@regionh.dk
Scientific contact	Michael Achiam, Dept. of Surgery and Transplantation, Rigshospitalet, Copenhagen University Hospital, +45 35450441, michael.patrick.achiam.01@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	31 August 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 July 2022
Global end of trial reached?	Yes
Global end of trial date	04 July 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to evaluate the safety of CaEP for esophageal cancer. Adverse Events (AE) and Serious Adverse Events (SAE) will be evaluated.

Protection of trial subjects:

Pain killers, medicine if side effects. Clinical out patient visits.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 June 2021
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: 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)	4
From 65 to 84 years	6
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment period: 1st of June 2021 - 7th of March 2022

Pre-assignment

Screening details:

16 patients were screend for inclusion of whom 10 were included. 8 of these 10 patients were treated.

Period 1

Period 1 title	Over all trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Treatment

Arm description:

Calcium electroporation

Arm type	Experimental
Investigational medicinal product name	Calcium
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intratumoral use

Dosage and administration details:

0.23 mmol/mL, max 20 mL

Number of subjects in period 1	Treatment
Started	10
Completed	8
Not completed	2
Physician decision	2

Baseline characteristics

Reporting groups	
Reporting group title	Over all trial
Reporting group description: 10	

Reporting group values	Over all trial	Total	
Number of subjects	10	10	
Age categorical Units: Subjects			
55-75	7	7	
>75	3	3	
Gender categorical			
sex			
Units: Subjects			
female	2	2	
male	8	8	

End points

End points reporting groups

Reporting group title	Treatment
Reporting group description:	
Calcium electroporation	

Primary: Safety

End point title	Safety[1]

End point description:

In five out of nine procedures, no adverse events were reported within the first 14 days. Two patients reported mild retrosternal pain (grade 1) the first days after treatment, one patient reported worsening anemia (grade 3), and one patient developed oral thrush (grade 2). Out of these events, one was considered a serious adverse event (one-day hospitalization due to anemia, requiring a single blood transfusion).

End point type	Primary

End point timeframe:

14 days after treatment.

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: Since it was only eight patients, only descriptive statistics was used.

End point values	Treatment			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: patients				
number (not applicable)	8			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: From treatment and 14 days after treatment.	
Assessment type	Systematic
Dictionary used	
Dictionary name	CTCAE
Dictionary version	5.0
Reporting groups	
Reporting group title	Treatment
Reporting group description: Calcium electroporation	

Serious adverse events	Treatment		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 8 (12.50%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Gastrointestinal disorders			
Worsening of anaemia, bleeding.			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Treatment		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 8 (37.50%)		
Gastrointestinal disorders			
Retrosternal pain (local pain close to tumor)			
subjects affected / exposed	2 / 8 (25.00%)		
occurrences (all)	2		
Infections and infestations			
Oral thrush			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	1		

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/36358702