



Clinical trial results:

Calcium electroporation for basal cell carcinomas – a 'Proof of concept' study

Summary

EudraCT number	2019-002730-36
Trial protocol	DK
Global end of trial date	29 June 2022

Results information

Result version number	v1 (current)
This version publication date	13 September 2023
First version publication date	13 September 2023

Trial information

Trial identification

Sponsor protocol code	CaEP68962
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Department of Dermatology, Bispebjerg Hospital
Sponsor organisation address	Nielsine Nielsens Vej 9, Copenhagen NV, Denmark, 2400
Public contact	Stine Regin Wiegell, Department of Dermatology, Bispebjerg Hospital, stine.regin.wiegell@regionh.dk
Scientific contact	Stine Regin Wiegell, Department of Dermatology, Bispebjerg Hospital, 0045 30914617, stine.regin.wiegell@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	30 August 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 June 2022
Global end of trial reached?	Yes
Global end of trial date	29 June 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Efficacy of calcium electroporation in the treatment of primary low risk basal cell carcinomas

Protection of trial subjects:

Local anaesthetics before electroporation

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 September 2019
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: 25
Worldwide total number of subjects	25
EEA total number of subjects	25

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	18
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

Recruited among patients referred to Bispebjerg hospital for the treatment of primary BCC

Pre-assignment

Screening details:

Patients referred to hospital for treatment of primary basal cell carcinoma

Period 1

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

Arms

Arm title	intervention
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Calciumchlorid "SAD"
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Cutaneous use

Dosage and administration details:

Injection of calcium chloride 9 mg/ml before electroporation

Number of subjects in period 1	intervention
Started	25
Completed	21
Not completed	4
Consent withdrawn by subject	2
Chemotherapy for internal cancer	1
Lost to follow-up	1

Baseline characteristics

Reporting groups

Reporting group title	intervention
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Reporting group description: -

Reporting group values	intervention	Total	
Number of subjects	25	25	
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)	5	5	
From 65-84 years	18	18	
85 years and over	2	2	
18-64 years	0	0	
Age continuous			
Units: years			
median	74		
full range (min-max)	50 to 93	-	
Gender categorical			
Units: Subjects			
Female	12	12	
Male	13	13	

End points

End points reporting groups

Reporting group title	intervention
Reporting group description: -	

Primary: Complete response

End point title	Complete response ^[1]
End point description:	

End point type	Primary
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End point timeframe:

3 months after last 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: No statistical analysis were possible due to the low number of patients treated (25) and only descriptive primary end point

End point values	intervention			
Subject group type	Reporting group			
Number of subjects analysed	24			
Units: Number of lesions in complete response	7			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

1 year after treatment

Assessment type	Non-systematic
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Dictionary used

Dictionary name	None
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Dictionary version	0
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Reporting groups

Reporting group title	Intervention
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Reporting group description: -

Serious adverse events	Intervention		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenectomy	Additional description: Removal of lymph node for diagnostics		
subjects affected / exposed	1 / 3 (33.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Infection			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Intervention		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)		
Skin and subcutaneous tissue disorders			
Necrosis			

subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Infections and infestations Erysipelas subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 2		

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