Clinical trial results:
Electrochemotherapy as a palliative treatment for brain metastases

Summary

EudraCT number	2010-023356-90
Trial protocol	DK
Global end of trial date	30 July 2013

Results information

Result version number	v1 (current)
This version publication date	29 August 2021
First version publication date	29 August 2021

Trial information

Trial identification

Sponsor protocol code	1020

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01322100
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Herlev Hospital
Sponsor organisation address	Herlev Ringvej 75, Herlev, Denmark, 2730
Public contact	Julie Gehl moved to Zealand University Hospital in 2017, Herlev Hospital, 45 93577626, kgeh@regionsjaelland.dk
Scientific contact	Julie Gehl moved to Zealand University Hospital in 2017, Herlev Hospital, 45 93577626, kgeh@regionsjaelland.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 July 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 July 2013
Global end of trial reached?	Yes
Global end of trial date	30 July 2013
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Primary endpoint is safety of the trial treatment, electrochemotherapy for brain metastases. This is evaluated by regularly registrations of adverse events (serious adverse events and adverse events) using the CTCAE criteria version 4.0.

Protection of trial subjects:

Written informed consent was mandatory for inclusion and patients were informed according to guidelines.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 April 2011
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: 1
Worldwide total number of subjects	1
EEA total number of subjects	1

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)	1
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Place of recruitment was the Department of Oncology at Herlev Hospital.

Pre-assignment

Screening details:

Patients with brain metastases from any solid tumor cancer. Patients must have been offered all standard treatments.

Period 1

Period 1 title	inclusion, treatment and follow-up (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Treatment

Arm description: -

Arm type	Experimental
Investigational medicinal product name	bleomycin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

15000 IU of bleomying/m2 BSA administered by infusion before delivery of electric pulses. Once only treatment.

Number of subjects in period 1	Treatment
Started	1
Completed	1

Baseline characteristics

Reporting groups	
Reporting group title	inclusion, treatment and follow-up

Reporting group description: -

Reporting group values	inclusion, treatment and follow-up	Total	
Number of subjects	1	1	
Age categorical Units: Subjects			
Adults (18-64 years)	1	1	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	1	1	
Male	0	0	

End points

End points reporting groups

Reporting group title	Treatment

Reporting group description: -

Primary: Safety

End point title	Safety[1]

End point description:

Adverse events and serious adverse events were reported according to CTCAE 4.0

End point type	Primary

End point timeframe:

From inclusion through treatment and follow-up period

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: Because only one subject was included in the trial statistical analysis can not be performed.

End point values	Treatment			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Adverse events	1			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: From inclusion through treatment and follow-up	
Assessment type	Systematic
Dictionary used	
Dictionary name	CTCAE
Dictionary version	4.0
Reporting groups	
Reporting group title	Treatment

Reporting group description: -

Serious adverse events	Treatment		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Treatment		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)		
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
Seizure	Additional description: One incident with brief seizure in the postoperative period was recorded		
subjects affected / exposed	1 / 1 (100.00%)		
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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The patient group to be included in this study were patients with brain metastases who had been offered all standard treatments. It was observed that recruitment was difficult and for this reason the trial was terminated after treatment of just 1 pt.

Notes: