Clinical trial results:
The efficacy of cabozantinib in advanced salivary gland cancer patients, a phase II clinical trial

Summary

EudraCT number	2018-000682-36
Trial protocol	NL
Global end of trial date	06 November 2019

Results information

Result version number	v1 (current)
This version publication date	24 June 2022
First version publication date	24 June 2022

Trial information

Trial identification

Sponsor protocol code	NL65109.091.18

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Radboud university medical center
Sponsor organisation address	Geert Grooteplein Zuid 10, Nijmegen, Netherlands,
Public contact	Hettie Maters, Radboud university medical center, hettie.maters@radboudumc.nl
Scientific contact	Hettie Maters, Radboud university medical center, hettie.maters@radboudumc.nl

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	06 November 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 November 2019
Global end of trial reached?	Yes
Global end of trial date	06 November 2019
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Assess the overall response rate (ORR) of cabozantinib in advanced salivary gland cancer patients. ORR is defined as the sum of the complete remissions plus partial responses. The best response will be used in each patient.

Protection of trial subjects:

In order to minimize risk of this experimental treatment, we took certain measures. First of all, only patients with a reasonable health (see inclusion criteria) can be included. Second,
we use the Simon 2-stage design in order to minimize exposure of patients in case of minimal efficacy. Third, we took standard precautions such as moderate monitoring according to NFU guidelines. And Finally, we will only include c-MET positive tumors in order to increase the chance of treatment efficacy.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 September 2018
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	Netherlands: 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)	18
From 65 to 84 years	7

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

general inclusion criteria
- Age ≥18 years
- Eastern Cooperative Oncology Group performance status of 0 or 1.
- adequate organ function

Period 1

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

Arms

Arm title	single arm

Arm description:

single arm

Arm type	Experimental
Investigational medicinal product name	cabozantinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60 mg once daily

Number of subjects in period 1	single arm
Started	25
Completed	25

Baseline characteristics

End points

End points reporting groups

Reporting group title	single arm

Reporting group description:

single arm

Primary: objective response rate

End point title	objective response rate[1]

End point description:

End point type	Primary

End point timeframe:

the best response from start of the trial until termination

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: in this single arm study no statistical analysis could be performed.

End point values	single arm			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: number of patients	25			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: whole trial	
Adverse event reporting additional description: CTCAE version 5	
Assessment type	Systematic

Dictionary used	
Dictionary name	CTCAE
Dictionary version	5

Reporting groups	
Reporting group title	trial

Reporting group description: -

Serious adverse events	trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 25 (48.00%)		
number of deaths (all causes)	18		
number of deaths resulting from adverse events	1		
General disorders and administration site conditions			
Anorexia nervosa			
subjects affected / exposed	1 / 25 (4.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Weight decreased			
subjects affected / exposed	1 / 25 (4.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
dehydration			
subjects affected / exposed	2 / 25 (8.00%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Hypertension			

subjects affected / exposed	4 / 25 (16.00%)		
occurrences causally related to treatment / all	4 / 4		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	2 / 25 (8.00%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 25 (4.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Tracheal fistula			
subjects affected / exposed	1 / 25 (4.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	1 / 1		
Skin and subcutaneous tissue disorders			
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	1 / 25 (4.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Skin ulcer			
subjects affected / exposed	1 / 25 (4.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 25 (100.00%)		

General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all)	 22 / 25 (88.00%) 22		
Gastrointestinal disorders Alanine aminotransferase increased subjects affected / exposed occurrences (all)	 17 / 25 (68.00%) 17		
Skin and subcutaneous tissue disorders Palmar-plantar erythrodysaesthesia syndrome subjects affected / exposed occurrences (all)	 16 / 25 (64.00%) 16		

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