Clinical trial results:
Selecting cancer patients for treatment using Tumor Organoids, the SENSOR study

Summary

EudraCT number	2014-003811-13
Trial protocol	NL
Global end of trial date	16 April 2019

Results information

Result version number	v1 (current)
This version publication date	20 June 2021
First version publication date	20 June 2021

Trial information

Trial identification

Sponsor protocol code	N14SNS

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	ABR : NL50400.031.14

Notes:

Sponsors

Sponsor organisation name	Antoni van Leeuwenhoek - Netherlands Cancer Institute
Sponsor organisation address	Plesmanlaan 121, Amsterdam, Netherlands,
Public contact	Emile Voest, Antoni van Leeuwenhoek - Netherlands Cancer Institute, +31 205129111, e.voest@nki.nl
Scientific contact	Emile Voest, Antoni van Leeuwenhoek - Netherlands Cancer Institute, +31 205129111, e.voest@nki.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	16 April 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 April 2019
Global end of trial reached?	Yes
Global end of trial date	16 April 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Evaluate the efficacy of patient-derived tumor organoids to successfully allocate patients for treatment with specific targeted agents.

Protection of trial subjects:

Histological biopsies were obtained with the same high quality standards as biopsy procedures in regular care.
Upon experimental treatment, patients were tightly monitored within a designated clinical research department (Clinical Research Unit).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 May 2016
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: 61
Worldwide total number of subjects	61
EEA total number of subjects	61

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)	44
From 65 to 84 years	17
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Metastatic colorectal cancer (CRC) patients without curative treatment options were accrued at The Netherlands Cancer Institute before start of their last SOC treatment

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	61
Number of subjects completed	6

Pre-assignment subject non-completion reasons

Reason: Number of subjects	No biopsy: 7
Reason: Number of subjects	Unsuccessful organoid culture: 23
Reason: Number of subjects	No drug screen performed: 6
Reason: Number of subjects	No hit in drug screen: 6
Reason: Number of subjects	No treatment started: 13

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Capivasertib

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Capivasertib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Orodispersible tablet
Routes of administration	Oral use

Dosage and administration details:

Twice daily, 125 mg in 28-day cycles using an intermittent dosing schedule (2 days on/5 days off)

Arm title	Vistusertib

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Vistusertib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Orodispersible tablet
Routes of administration	Oral use

Dosage and administration details:

Twice daily, at a dose of 480 mg in 28-day cycles using an intermittent dosing schedule (4 days on/3

days off)

Number of subjects in period 1[1]	Capivasertib	Vistusertib
Started	3	3
Completed	1	3
Not completed	2	0
Lack of efficacy	2	-

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: There was a high drop-out of patients before initiating treatment within the trial. This is explained in the pre-assignement period

Baseline characteristics

Reporting groups

Reporting group title	Treatment

Reporting group description: -

Reporting group values	Treatment	Total	
Number of subjects	6	6	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
median	57		
full range (min-max)	51 to 65	-	
Gender categorical Units: Subjects			
Female	3	3	
Male	3	3	

End points

End points reporting groups

Reporting group title	Capivasertib
Reporting group description: -	
Reporting group title	Vistusertib
Reporting group description: -	

Primary: Objective response rate

End point title	Objective response rate[1]
End point description:	
End point type	Primary
End point timeframe:	
Response evaluation	

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: Please see final manuscript at PMID:33887686

End point values	Capivasertib	Vistusertib		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	3		
Units: 20%				
Objective response (RECIST 1.1)	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: Anytime during treatment	
Assessment type	Systematic

Dictionary used	
Dictionary name	CTCAE
Dictionary version	5.0

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

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: Please see final manuscript at PMID:33887686

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/33887686