



Clinical trial results:

Individualizing Pazopanib therapy by explorIng the role of Early metabolic responsE and drug exposure as a preDICTor for treatment outcome in patients with STS

Summary

EudraCT number	2013-003533-16
Trial protocol	NL
Global end of trial date	24 November 2017

Results information

Result version number	v1 (current)
This version publication date	12 June 2021
First version publication date	12 June 2021
Summary attachment (see zip file)	Medical Journal Article (Vlenterie PREDICT AnticancerResearch 2019.pdf)

Trial information

Trial identification

Sponsor protocol code	UMCN-ONCO-201303
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01995981
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Radboud University Nijmegen Medical Centre
Sponsor organisation address	Geert Grooteplein 10, Nijmegen, Netherlands,
Public contact	Research verpleegkundigen oncologie, Radboud University Nijmegen Medical Centre, 0031 243610353,
Scientific contact	Research verpleegkundigen oncologie, Radboud University Nijmegen Medical Centre, 0031 243610353,

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	03 December 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 May 2017
Global end of trial reached?	Yes
Global end of trial date	24 November 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate whether early metabolic response is correlated to clinical benefit. And to evaluate the effect of age on pazopanib pharmacokinetics.

Protection of trial subjects:

The study included additional PETscans and PK analysis for which only one IV line was used.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 October 2013
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	Netherlands: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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)	12
From 65 to 84 years	8
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment in the Radboud University Medical Center in Nijmegen and the Antoni van Leeuwenhoek – Netherlands Cancer Institute in Amsterdam

Pre-assignment

Screening details:

Inclusion and exclusion criteria were similar to those used in the PALETTE trial: van der Graaf WT, et al. Pazopanib for metastatic soft tissue sarcoma (PALETTE): a randomised, double-blind, placebo-controlled phase 3 trial. Lancet 379: 1879-1886, 2012. PMID: 22595799.

Period 1

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

Blinding implementation details:

N/A

Arms

Arm title	FDG-PET
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Arm description:

The study was designed as a prospective observational feasibility study

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

Dosage and administration details:

800 mg pazopanib once daily

Number of subjects in period 1	FDG-PET
Started	20
Completed	20

Baseline characteristics

Reporting groups

Reporting group title	Inclusion
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Reporting group description: -

Reporting group values	Inclusion	Total	
Number of subjects	20	20	
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	60		
full range (min-max)	40 to 78	-	
Gender categorical			
Units: Subjects			
Female	11	11	
Male	9	9	

End points

End points reporting groups

Reporting group title	FDG-PET
Reporting group description: The study was designed as a prospective observational feasibility study	
Subject analysis set title	PK AUC0-24h
Subject analysis set type	Full analysis
Subject analysis set description: AUC 0-24h	
Subject analysis set title	PK Ctrough
Subject analysis set type	Full analysis
Subject analysis set description: Ctrough levels	

Primary: FDG-PET/CT can be used for early monitoring of response to pazopanib treatment in STS patients

End point title	FDG-PET/CT can be used for early monitoring of response to pazopanib treatment in STS patients ^[1]
End point description:	
End point type	Primary
End point timeframe: 10-10-2013 - 26-5-2017	

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 analyses were performed as this was a pilot observational study. Only descriptives were given.

Statistical analyses

No statistical analyses for this end point

Primary: there is an association between FDG-PET/CT response and pazopanib concentration/exposure

End point title	there is an association between FDG-PET/CT response and pazopanib concentration/exposure ^[2]
End point description:	
End point type	Primary
End point timeframe: oct 2013- may 2017	

Notes:

[2] - 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 analyses were performed as this was a pilot observational study. Only descriptives were given.

End point values	FDG-PET			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Response	20			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

oct 2013 - may 2017

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCTAE
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Dictionary version	4.0
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Reporting groups

Reporting group title	Patiënts
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Reporting group description: -

Serious adverse events	Patiënts		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 20 (15.00%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Hepatobiliary disorders			
Elevated liver enzymes			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Dyspneu	Additional description: Due to disease progression		
subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		

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

Non-serious adverse events	Patiënts		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 20 (65.00%)		
Vascular disorders			
Hypertension			

subjects affected / exposed occurrences (all)	5 / 20 (25.00%) 5		
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all)	10 / 20 (50.00%) 10		
Gastrointestinal disorders Decreased appetite due to nausea/altered taste subjects affected / exposed occurrences (all)	8 / 20 (40.00%) 8		

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/30842163>