Clinical trial results:
Lean Body Mass as a determinant of docetaxel pharmacokinetics and toxicity (LEANDOC)

Summary

EudraCT number	2011-005168-14
Trial protocol	NL
Global end of trial date	01 August 2016

Results information

Result version number	v1 (current)
This version publication date	21 September 2019
First version publication date	21 September 2019

Trial information

Trial identification

Sponsor protocol code	UMCN-AKF11.01

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Radboudumc
Sponsor organisation address	Geert Grooteplein Zuid 10, Nijmegen, Netherlands,
Public contact	Angela Colbers, Radboud University Nijmegen Medical Centre, angela.colbers@radboudumc.nl
Scientific contact	Angela Colbers, Radboud University Nijmegen Medical Centre, angela.colbers@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	01 August 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 August 2015
Global end of trial reached?	Yes
Global end of trial date	01 August 2016
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To determine which anthropometric parameters, LBM, total body weight (TBW) or BSA correlates best to docetaxel exposure (AUC) for both males and females.

Protection of trial subjects:

Subjects experience only limited burden or risk during study related assessments of one DEXA scan, one BIA measurement and withdrawal of 4 pharmacokinetic blood samples. Subjects will not have direct benefit of participating in the study.
Subjects may experience side effects of the medication administered for the treatment of cancer. The choice for treatment will be made by their treating physician, this will not be influenced by this study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 May 2012
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: 32
Worldwide total number of subjects	32
EEA total number of subjects	32

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)	26
From 65 to 84 years	6

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

32 patients included in 2 centres in the Netherlands

Pre-assignment

Screening details:

Subjects who are diagnosed with breast or metastatic castration-resistant prostate carcinoma who will receive docetaxel containing treatment according to standard hospital protocol

Period 1

Period 1 title	screening
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	docetaxel

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	docetaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

20mg/mL

Number of subjects in period 1	docetaxel
Started	32
Completed	23
Not completed	9
Physician decision	9

Period 2

Period 2 title	PK day
Is this the baseline period?	Yes[1]
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	docetaxel
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	docetaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

20mg/mL

Notes:

[1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: baseline was performed on PK day, not at screening.

Number of subjects in period 2[2]	docetaxel
Started	23
Completed	23

Notes:

[2] - 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: we do not have these data in the database from the patients screened but not included.

Baseline characteristics

Reporting groups	
Reporting group title	PK day

Reporting group description: -

Reporting group values	PK day	Total	
Number of subjects	23	23	
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			
arithmetic mean	57		
full range (min-max)	31.5 to 77.8	-	
Gender categorical Units: Subjects			
Female	18	18	
Male	5	5	

End points

End points reporting groups

Reporting group title	docetaxel
Reporting group description: -	
Reporting group title	docetaxel
Reporting group description: -	

Primary: correlation with BSA

End point title	correlation with BSA[1]
End point description:	
correlation dosing on BSA and docetaxel clearance	
End point type	Primary
End point timeframe:	
entire study	

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: correlation between AUC and TBW was done, it is not possible to put that analysis in the statics fields. Pearson correlation coefficients were reported, p value all >0.05

End point values	docetaxel			
Subject group type	Reporting group			
Number of subjects analysed	23			
Units: number				
number (not applicable)	-0.326			

Statistical analyses

No statistical analyses for this end point

Primary: Correlation LBM

End point title	Correlation LBM[2]
End point description:	
correlation dosing on LBM and docetaxel clearance	
End point type	Primary
End point timeframe:	
entire study	

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: correlation between AUC and BSA was done, it is not possible to put that analysis in the statics fields. Pearson correlation coefficients were reported, p value all >0.05

End point values	docetaxel			
Subject group type	Reporting group			
Number of subjects analysed	23			
Units: number				
number (not applicable)	-0.171			

Statistical analyses

No statistical analyses for this end point

Primary: correlation TBW

End point title	correlation TBW[3]

End point description:

correlation dosing on TBW and docetaxel clearance

End point type	Primary

End point timeframe:

entire study

Notes:

[3] - 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: correlation between AUC and LBM was done, it is not possible to put that analysis in the statics fields. Pearson correlation coefficients were reported, p value all >0.05

End point values	docetaxel			
Subject group type	Reporting group			
Number of subjects analysed	23			
Units: number				
number (not applicable)	-0.336			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: entire study	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	none
Dictionary version	1

Reporting groups	
Reporting group title	LEANDOC

Reporting group description: -

Serious adverse events	LEANDOC		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 23 (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	LEANDOC		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 23 (0.00%)		

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: no adverse events were reported.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 December 2013	In the synopsis the requirement of 20 female breast carcinoma patients and 20 castration resistant prostate carcinoma patients has been changed. We will include 40 subjects either patients with breast carcinoma or castration resistant prostate carcinoma which receive docetaxel as part of their treatment.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
01 August 2016	trial was stopped due to very slow recruitment.	-

Notes:

Limitations and caveats

None reported