



Clinical trial results:

A phase II study in mCRPC on the pharmacodynamic effects of budesonide on cabazitaxel (Jevtana®): A randomised, open-label multicenter study: CABARESC

Summary

EudraCT number	2011-003346-40
Trial protocol	NL
Global end of trial date	30 October 2015

Results information

Result version number	v1 (current)
This version publication date	22 January 2020
First version publication date	22 January 2020
Summary attachment (see zip file)	Paper on results (1679.full.pdf) Latest amended protocol (140807-CABARESC protocol v5 amendment met track changes versie 7-8-2014.pdf)

Trial information

Trial identification

Sponsor protocol code	CABARESC
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Erasmus MC
Sponsor organisation address	's Gravendijkwal 230, Rotterdam, Netherlands,
Public contact	Department of Medical Oncology, Roo, Erasmus MC-Daniël den Hoed, +31 107041338NA, a.mathijssen@erasmusmc.nl
Scientific contact	Department of Medical Oncology, Roo, Erasmus MC-Daniël den Hoed, +31 107041338NA, a.mathijssen@erasmusmc.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	30 October 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 October 2015
Global end of trial reached?	Yes
Global end of trial date	30 October 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To study the effects of budesonide on the incidence of cabazitaxel induced diarrhea

Protection of trial subjects:

See study protocol (attached)

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 September 2011
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: 246
Worldwide total number of subjects	246
EEA total number of subjects	246

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)	59
From 65 to 84 years	187
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Patients planned to start with cabazitaxel therapy were screened for the inclusion and exclusion criteria.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Budesonide

Arm description: -

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

Dosage and administration details:

Budesonide will be administered once daily in the morning, one hour before breakfast as oral medication consisting three capsules (3x3 mg), during 44 consecutive days, beginning two days before the first cycle of cabazitaxel. In case of delay of cabazitaxel, budesonide should be continued unless this is contraindicated. . Patient compliance will be assessed through a (short) patient diary

Arm title	Control
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Arm description:

Cabazitaxel without budesonide

Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	Budesonide	Control
Started	122	124
Completed	114	113
Not completed	8	11
Cabazitaxel dose too low	1	5
Cabazitaxel not started	7	4
Protocol deviation	-	2

Baseline characteristics

End points

End points reporting groups

Reporting group title	Budesonide
Reporting group description:	-
Reporting group title	Control
Reporting group description:	Cabazitaxel without budesonide

Primary: incidence of grade 2–4

End point title	incidence of grade 2–4
End point description:	
End point type	Primary
End point timeframe:	First two cycles of cabazitaxel (i.e. the complete study period)

End point values	Budesonide	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	114	113		
Units: persons	21	14		

Statistical analyses

Statistical analysis title	X2 primary endpoint
Comparison groups	Control v Budesonide
Number of subjects included in analysis	227
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.21
Method	Chi-squared

Secondary: other cabazitaxel-induced adverse events

End point title	other cabazitaxel-induced adverse events
End point description:	
End point type	Secondary
End point timeframe:	Complete study period

End point values	Budesonide	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	114	113		
Units: persons	114	113		

Statistical analyses

No statistical analyses for this end point

Secondary: PSA response

End point title	PSA response
End point description:	
End point type	Secondary
End point timeframe:	
complete study	

End point values	Budesonide	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	114	113		
Units: persons	31	38		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

complete study

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCAE
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Dictionary version	4.03
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Frequency threshold for reporting non-serious adverse events: 0 %

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: Adverse event data (of both serious and non-serious adverse events) are reported extensively in the attached published paper

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 February 2012	Addition of blood withdrawal for side study on circulating tumor cells

Notes:

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/27702823>