Clinical trial results:
Tocotrienol as a nutritional supplement in patients with advanced ovarian cancer

Summary

EudraCT number	2013-004858-18
Trial protocol	DK
Global end of trial date	02 July 2019

Results information

Result version number	v1 (current)
This version publication date	16 December 2020
First version publication date	16 December 2020

Trial information

Trial identification

Sponsor protocol code	Toco-Ovar

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02399592
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Vejle Hospital
Sponsor organisation address	Beriderbakken 4, Vejle, Denmark,
Public contact	Klinisk Forskningsenhed, Vejle Hospital, +45 79406010, anders.jakobsen@rsyd.dk
Scientific contact	Klinisk Forskningsenhed, Vejle Hospital, +45 79406010, anders.jakobsen@rsyd.dk

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	11 September 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 July 2019
Global end of trial reached?	Yes
Global end of trial date	02 July 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the effect of tocotrienol as a nutritional supplement in combination with bevacizumab in patients with advanced ovarian cancer

Protection of trial subjects:

None

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 January 2014
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	Denmark: 23
Worldwide total number of subjects	23
EEA total number of subjects	23

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)	16
From 65 to 84 years	7
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Danish patients with advanced ovarian cancer recruited in the outpatient setting.

Pre-assignment

Screening details:

Patients with advanced ovarian cancer without other treatment options.

Period 1

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

Blinding implementation details:

N/A

Arms

Arm title	Tocotrienol

Arm description: -

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

Dosage and administration details:

300 mg x 3 daily orally

Number of subjects in period 1	Tocotrienol
Started	23
Completed	23

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	23	23	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	16	16	
From 65-84 years	7	7	
85 years and over	0	0	
Age continuous Units: years			
median	71		
full range (min-max)	41 to 81	-	
Gender categorical Units: Subjects			
Female	23	23	
Male	0	0	

End points

End points reporting groups

Reporting group title	Tocotrienol

Reporting group description: -

Primary: Fraction of patients without progression after six months of treatment

End point title	Fraction of patients without progression after six months of treatment[1]

End point description:

End point type	Primary

End point timeframe:

6 months after start of treatment

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: There is only one group in this study and hence no possibility for comparison and statistics in relation to the primary endpoint.

End point values	Tocotrienol			
Subject group type	Reporting group			
Number of subjects analysed	23			
Units: Percentage				
number (not applicable)	16			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Before start of each treatment cycle, i.e. every three weeks

Adverse event reporting additional description:

AEs graded according to CTCAE version 4.0

Assessment type	Systematic

Dictionary used

Dictionary name	CTCAE
Dictionary version	4.0

Reporting groups

Reporting group title	Toxicity

Reporting group description: -

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: There were no non-serious grade 3/4 adverse events in the study.

Serious adverse events	Toxicity		
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 23 (52.17%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Investigations			
Blood bilirubin increased			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pain			

subjects affected / exposed	1 / 23 (4.35%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Performance status decreased				
subjects affected / exposed	3 / 23 (13.04%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Abdominal pain				
subjects affected / exposed	4 / 23 (17.39%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	2 / 23 (8.70%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	1 / 23 (4.35%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	2 / 23 (8.70%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	1 / 23 (4.35%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Dyspnoea				
subjects affected / exposed	2 / 23 (8.70%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			

Pleural effusion			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
FEV1/FVC ratio			
subjects affected / exposed	2 / 23 (8.70%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Infection			
subjects affected / exposed	3 / 23 (13.04%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 4 %

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

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