Clinical trial results:
Reintroduction of platinum-based therapy after treatment with trabectedin in patients with relapsed ovarian cancer resistant to platinum

Summary

EudraCT number	2014-004020-21
Trial protocol	ES
Global end of trial date	16 January 2018

Results information

Result version number	v1 (current)
This version publication date	24 April 2021
First version publication date	24 April 2021
Summary attachment (see zip file)	Resumen en español (resumen.pdf)

Trial information

Trial identification

Sponsor protocol code	PR-Trab-PT

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Fundación Investigación Biomédica Hospital Clínico San Carlos
Sponsor organisation address	Profesor Martin Lagos s/n , Madrid, Spain, 28040
Public contact	ana belen rivas paterna, UICEC, 0034 913303000ext7360, fibucicec.hcsc@saldud.madrid.org
Scientific contact	ana belen rivas paterna, UICEC, 91330373 913303000ext7360, fibucicec.hcsc@saldud.madrid.org

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	13 December 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 January 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Objective response rate and time to pathology progression (assessed according to RECIST 1.1)

Protection of trial subjects:

Follow up for 4 months after the treatment finished

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 January 2015
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	Spain: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

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)	5
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment started on June 2015 and finished on December 2017

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	10
Number of subjects completed	10

Period 1

Period 1 title	treatment period (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Trabectidine

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Yondelis
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

1,3 mg/m2

Number of subjects in period 1	Trabectidine
Started	10
Completed	10

Baseline characteristics

Reporting groups	
Reporting group title	Trabectidine

Reporting group description: -

Reporting group values	Trabectidine	Total	
Number of subjects	10	10	
Age categorical			
Adults			
Units: Subjects			
Adults (18-64 years)	5	5	
From 65-84 years	5	5	
85 years and over	0	0	
Age continuous			
Adults 18-80			
Units: years			
median	64.35		
standard deviation	± 8.55	-	
Gender categorical			
Women			
Units: Subjects			
Female	10	10	
Male	0	0	

End points

End points reporting groups

Reporting group title	Trabectidine

Reporting group description: -

Primary: The primary end points of the study were to compare time to first progression with platinum pre-trabectedin (TTP1) with time to second progression with platinum post-trabectedin (TTP2)

End point title	The primary end points of the study were to compare time to first progression with platinum pre-trabectedin (TTP1) with time to second progression with platinum post-trabectedin (TTP2)[1]

End point description:

End point type	Primary

End point timeframe:

time to second progression with platinum post-trabectedin

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: For the primary evaluation criterion, the objective response rate (TR) It was carried out by a Bayesian analysis. The Bayes quadratic loss estimator with its confidence interval (CI, credible region) also was analysed.
Only one arm.

End point values	Trabectidine			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: weeks				
number (not applicable)	10			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From the signing of the informed consent until 30 days after the suspension of the investigational product.	
Assessment type	Systematic

Dictionary used	
Dictionary name	CTCAE
Dictionary version	4.3

Reporting groups	
Reporting group title	Asthenia
Reporting group description:	
Only one patient shown asthenia during the treatment	

Serious adverse events	Asthenia		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Asthenia		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 10 (10.00%)		
Nervous system disorders			
Asthenia			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
30 September 2016	Changes in inclusion ans exclusion criterias
27 January 2017	Protocol: Changes in inclusion and dose criterias. ICF: Patient Information Updated
16 January 2018	Investigator´s brochure update

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported