Clinical trial results:
Sentinel node in ovarian cáncer: tailoring clinical feasibility

Summary

EudraCT number	2017-003683-12
Trial protocol	ES
Global end of trial date	21 August 2019

Results information

Result version number	v1 (current)
This version publication date	13 February 2022
First version publication date	13 February 2022
Summary attachment (see zip file)	SENTOV result publication (PUBLICACION SENTOV_2020.pdf)

Trial information

Trial identification

Sponsor protocol code	SENTOV

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Instituto de Investigación Sanitaria La Fe de Valencia
Sponsor organisation address	Avenida Fernando Abril Martorell, Torre 106 A 7planta, Valencia, Spain,
Public contact	Jose María Millan Salvador , Instituto de Investigación Sanitaria La Fe, 34 961246611, investigacion_clinica@iislafe.es
Scientific contact	Jose María Millan Salvador, Instituto de Investigación Sanitaria La Fe, 34 961246611, investigacion_clinica@iislafe.es

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	06 November 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	21 August 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To describe the feasibility of performing the Sentinel Node technique (Sentinel Node detection rate) in patients with previous ovarian surgery by injecting the tracer into the stump of the infundibular-pelvic ligament and uterus-ovarian ligament

Protection of trial subjects:

The reference study was conducted in Spain under the legal framework of Royal Decree 1090/2015. It has been performed in accordance with the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, adopted by the General Assembly of the World Medical Association (1996). In addition, the study has been conducted in accordance with the protocol, good clinical practice (GCP) in accordance with the guidelines of the international conference on harmonization (ICH) and regulatory requirements for participating institutions.
An appropriately performed informed consent has been used, in compliance with GCP according to ICH guidelines and approved by the CEIm of the Hospital Universitario y Politécnico La Fe. Prior to inclusion of subjects in the study, a copy of the CEIm-approved informed consent has been reviewed with the prospective participant, signed and dated. The investigator has provided a copy of each subject's signed informed consent form and has retained a copy in the subject's study file.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 March 2018
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: 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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	20
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients diagnosed with ovarian cancer at apparent stage I-II

Pre-assignment

Screening details:

Inclusion criteria:
Signed informed consent prior to the performance of any procedure related to the clinical trial.
Women 18 years of age or older at the time of inclusion.
Patients with an anatomopathological diagnosis of malignant ovarian tumor in deferred study proposed for staging surgery or patients with tumor suspicious of malignancy

Pre-assignment period milestones

Number of subjects started	20
Number of subjects completed	20

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Previous confirmed malignancy

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	m99Tc
Investigational medicinal product code	
Other name	technetium 99m nanocolloid
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Injection , Intravenous use

Dosage and administration details:

Subperitoneal injection 0.2ml of saline solution with 37 mBq

Investigational medicinal product name	Indocyanine green
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Injection

Dosage and administration details:

Subperitoneal injection at a concentration of 1,25 mg/mL. One vial of 25 mg diluted in 20 ml of serum injecting extra 0,5 mL of the solution together with the radioactive colloid.

Arm title	Suspicious adnexal mass

Arm description: -

Arm type	Experimental

Investigational medicinal product name	m99Tc
Investigational medicinal product code	
Other name	technetium 99m nanocolloid
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Injection , Intravenous use

Dosage and administration details:

Subperitoneal injection 0.2ml of saline solution with 37 mBq

Investigational medicinal product name	Indocyanine green
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Pharmaceutical forms	Injection
Routes of administration	Injection

Dosage and administration details:

Subperitoneal injection at a concentration of 1,25 mg/mL. One vial of 25 mg diluted in 20 ml of serum injecting extra 0,5 mL of the solution together with the radioactive colloid.

Number of subjects in period 1	Previous confirmed malignancy	Suspicious adnexal mass
Started	9	11
Completed	9	11

Baseline characteristics

Reporting groups	
Reporting group title	Previous confirmed malignancy
Reporting group description: -	
Reporting group title	Suspicious adnexal mass
Reporting group description: -	

Reporting group values	Previous confirmed malignancy	Suspicious adnexal mass	Total
Number of subjects	9	11	20
Age categorical Units: Subjects			
Adults from 35-68	9	11	20
Gender categorical Units: Subjects			
Female	9	11	20
Male	0	0	0
Approach Units: Subjects			
Laparoscopy	9	0	9
Laparotomy	0	11	11
Diagnosis Units: Subjects			
Confirmed	9	0	9
Suspicious	0	11	11

End points

End points reporting groups	
Reporting group title	Previous confirmed malignancy
Reporting group description: -	
Reporting group title	Suspicious adnexal mass
Reporting group description: -	

Primary: Feasibility of performing the sentinel lymph node technique	
End point title	Feasibility of performing the sentinel lymph node technique
End point description:	
End point type	Primary
End point timeframe:	
Perioperative length	

End point values	Previous confirmed malignancy	Suspicious adnexal mass		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	11		
Units: Percentage %	100	100		

Statistical analyses

Statistical analysis title	T-Test
Comparison groups	Suspicious adnexal mass v Previous confirmed malignancy
Number of subjects included in analysis	20
Analysis specification	Pre-specified
Analysis type	superiority
P-value	≤ 0.05
Method	t-test, 1-sided
Parameter estimate	Mean difference (final values)
Point estimate	90
Confidence interval	
level	95 %
sides	1-sided
upper limit	100
Variability estimate	Standard deviation
Dispersion value	1.5

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

All events that meet the definition of an AA and occur within the period from the time the patient signs the informed consent form until 28 days after the end of treatment must be recorded.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Study population

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 are no non-serious adverse events recorded in the final result report

Serious adverse events	Study population		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 20 (10.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Vaginal lesion	Additional description: vaginal vault dehiscence		
subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Intestinal obstruction			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Study population		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 20 (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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/32448808