Clinical trial results:
Intraoperative intraperitoneal chemoperfusion to treat peritoneal minimal residual disease in stage III ovarian cancer: a randomized phase II trial.

Summary

EudraCT number	2015-000418-23
Trial protocol	BE
Global end of trial date	25 August 2021

Results information

Result version number	v1 (current)
This version publication date	06 June 2024
First version publication date	06 June 2024
Summary attachment (see zip file)	Final Study Report (2015-000418-23_OVIP_Final Study Report_27072022.pdf) Protocol (2015-0572 Protocol_V1_17Feb2015.pdf) ClinicalTrials.gov (ClinicalTrials-Gov.pdf) Summary attachment (OVIP_brjsurg.docx)

Trial information

Trial identification

Sponsor protocol code	AGO/2015/002

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	UZ Ghent
Sponsor organisation address	C. Heymanslaan 10, Gent, Belgium, 9000
Public contact	Bimetra Clinics, Ghent University Hospital, +32 93320500, bimetra.clinics@uzgent.be
Scientific contact	Bimetra Clinics, Ghent University Hospital, +32 93320500, bimetra.clinics@uzgent.be

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	25 August 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	25 August 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To study the effect of cytoreductive surgery (CRS) and efficacy of cisplatin-based intraoperative intraperitoneal chemoperfusion (IPEC) in patients with primary or recurrent serous epithelial ovarian cancer (OC), in order to treat peritoneal minimal residual disease (pMRD).

Protection of trial subjects:

See attachment Final Status Report

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 March 2016
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	Belgium: 56
Worldwide total number of subjects	56
EEA total number of subjects	56

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)	56
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

See attachement Final Study Report

Pre-assignment

Screening details:

See attachement Final Study Report

Period 1

Period 1 title	Period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind[1]
Roles blinded	Subject, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	low dose, normothermic

Arm description:

CRS + normothermic (37°C) intraoperative intraperitoneal chemoperfusion, with 100mg/m² Cisplatin during 90min + adjuvant chemotherapy

Arm type	Experimental
Investigational medicinal product name	IPEC with Cisplatin (75mg/m²)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for intravesical solution
Routes of administration	Other use

Dosage and administration details:

See attachements

Arm title	high dose, normothermic

Arm description:

CRS + normothermic (37°C) intraoperative intraperitoneal chemoperfusion, with 75mg/m² Cisplatin during 90min + adjuvant chemotherapy

Arm type	Experimental
Investigational medicinal product name	IPEC with Cisplatin (100mg/m²)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection/infusion
Routes of administration	Other use

Dosage and administration details:

Intraperitoneal normotherm (37°C) administration of Cisplatin (100mg/m²), during 90min

Arm title	low dose, hyperthermic

Arm description:

CRS + hyperthermic (41°C) intraoperative intraperitoneal chemoperfusion, with 75mg/m² Cisplatin during 90min + adjuvant chemotherapy

Arm type	Experimental

Investigational medicinal product name	Hypertherm IntraPEritoneal Chemotherapy with Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Other use

Dosage and administration details:

Intraperitoneal hypertherm (41°C) administration of Cisplatin (75mg/m²), during 90min

Arm title	high dose, hyperthermic

Arm description:

CRS + hyperthermic (41°C) intraoperative intraperitoneal chemoperfusion, with 100mg/m² Cisplatin during 90min + adjuvant chemotherapy

Arm type	Experimental
Investigational medicinal product name	HIPEC with Cisplatin (100mg/m²)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Other use

Dosage and administration details:

Intraperitoneal hypertherm (41°C) administration of Cisplatin (100mg/m²), during 90min

Notes:

[1] - The number of roles blinded appears inconsistent with a single blinded trial. It is expected that there will be one role blinded in a single blind trial.
Justification: zie attachments

Number of subjects in period 1[2]	low dose, normothermic	high dose, normothermic	low dose, hyperthermic
Started	16	12	13
Completed	16	12	13

Number of subjects in period 1[2]	high dose, hyperthermic
Started	13
Completed	13

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: see attachments

Baseline characteristics

End points

End points reporting groups

Reporting group title	low dose, normothermic
Reporting group description:	
CRS + normothermic (37°C) intraoperative intraperitoneal chemoperfusion, with 100mg/m² Cisplatin during 90min + adjuvant chemotherapy	
Reporting group title	high dose, normothermic
Reporting group description:	
CRS + normothermic (37°C) intraoperative intraperitoneal chemoperfusion, with 75mg/m² Cisplatin during 90min + adjuvant chemotherapy	
Reporting group title	low dose, hyperthermic
Reporting group description:	
CRS + hyperthermic (41°C) intraoperative intraperitoneal chemoperfusion, with 75mg/m² Cisplatin during 90min + adjuvant chemotherapy	
Reporting group title	high dose, hyperthermic
Reporting group description:	
CRS + hyperthermic (41°C) intraoperative intraperitoneal chemoperfusion, with 100mg/m² Cisplatin during 90min + adjuvant chemotherapy	

Primary: Primary

End point title	Primary[1]
End point description:	

End point type	Primary
End point timeframe:	
1 tumor nodule will be immediately fixed in liquid nitrogen after cytoreductive surgery and chemoperfusion. Frozen sections will be ablated through study completion	
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: See attachments	

End point values	low dose, normothermic	high dose, normothermic	low dose, hyperthermic	high dose, hyperthermic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	12	13	13
Units: LA-ICP-MS				
number (not applicable)	16	12	13	13

Statistical analyses

No statistical analyses for this end point

Secondary: Secondary

End point title	Secondary
End point description:	

End point type	Secondary

End point timeframe:

Surgical morbidity and mortality will be measured using Dindo-Clavien classification
This will be estimated with the Dindo-Clavien classification

[Time Frame: Within 30 days after surgery and intraoperative intraperitoneal chemoperfusion]
Cancer-spec

End point values	low dose, normothermic	high dose, normothermic	low dose, hyperthermic	high dose, hyperthermic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	12	13	13
Units: Subjects	16	12	13	13

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
During the study	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	0

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

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: See attachments

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