



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/m ²) |
| 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/m ²) |
| 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/m ²), 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/m ²) |
| 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/m ² Cisplatin during 90min + adjuvant chemotherapy | |
| Reporting group title | high dose, normothermic |
| Reporting group description: CRS + normothermic (37°C) intraoperative intraperitoneal chemoperfusion, with 75mg/m ² Cisplatin during 90min + adjuvant chemotherapy | |
| Reporting group title | low dose, hyperthermic |
| Reporting group description: CRS + hyperthermic (41°C) intraoperative intraperitoneal chemoperfusion, with 75mg/m ² Cisplatin during 90min + adjuvant chemotherapy | |
| Reporting group title | high dose, hyperthermic |
| Reporting group description: CRS + hyperthermic (41°C) intraoperative intraperitoneal chemoperfusion, with 100mg/m ² 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