

Treatment of advanced ovarian cancer with peritoneal carcinomatosis by laparoscopic delivery of chemotherapeutic agents

| | | |
|--|---|---|
| Submission date 09/03/2026 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 09/03/2026 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 09/03/2026 | Condition category Cancer | <input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)

Principal investigator, Scientific, Public

Contact name

Dr Alexey Dzasokhov

ORCID ID

<https://orcid.org/0000-0003-4977-3533>

Contact details

Moscow Regional Oncological Dispensary
6 Karbysheva Str.
Balashikha
Russian Federation
143900
+7 9037850613
dzasokhov-pipac@mail.ru

Additional identifiers

Study information

Scientific Title

Adjuvant Pressurized Intraperitoneal Aerosol Chemotherapy (PIPAC) in Suboptimally Cytoreduced Advanced Ovarian Cancer:
A Randomized Phase II Trial (PIPAC-OVA)

Study objectives

Ethics approval required

Ethics approval required

Ethics approval(s)

submitted 09/04/2021, Ethics Committee and the Scientific Council of the P.A. Hertsen Moscow Cancer Research Institute (125284, Moscow, 2nd Botkinsky proezd, 3, Moscow, 125284, Russian Federation; +7 495 150-11-22; mnoi@mail.ru), ref: protocol #661

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Parallel

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Suboptimally cytoreduced advanced ovarian cancer

Interventions

All patients underwent primary cytoreductive surgery, including total hysterectomy, bilateral adnexectomy, and omentectomy, with peritoneal biopsies obtained at laparotomy. No extended surgery (bowel resection, peritonectomy, etc.) was performed.

Patients were randomly assigned (1:1) intraoperatively to receive either standard systemic chemotherapy alone or systemic chemotherapy plus adjuvant pressurized intraperitoneal aerosol chemotherapy (PIPAC). Patient randomization was carried out using the website random.org.

Systemic chemotherapy consisted of paclitaxel (175 mg/m²) and carboplatin (AUC 5–7) administered every 3 weeks for six cycles. In the experimental arm, patients additionally

received three PIPAC procedures with cisplatin (10.5 mg/m²) and doxorubicin (2.1 mg/m²), administered immediately after cytoreduction and before the third and fifth chemotherapy cycles.

The primary endpoint was progression-free survival (PFS), defined as the time from cytoreductive surgery to disease progression or death from any cause. Secondary end points included overall survival (OS), CA-125 response, local peritoneal disease control, and safety.

Radiologic assessments with CT or MRI and serum CA-125 measurements were performed at baseline, during treatment, and at regular intervals during follow-up. In the PIPAC group, protocol-mandated diagnostic laparoscopy at 6 months included reassessment of the peritoneal cancer index (PCI) and repeat peritoneal biopsy for histologic evaluation. Adverse events were graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events, version 5.0.

The primary efficacy analyses were conducted according to the modified intention-to-treat (mITT) principle, including all randomized patients in their assigned groups (n=186), excluding 4 patients with a diagnosis other than EOC on definitive histology. Patients who withdrew consent were censored on the date of withdrawal (for time-to-event endpoints) and contributed follow-up time up to that date. Safety analyses were performed in the as-treated population, defined as all patients who received at least one component of the allocated treatment (n=169).

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Progression-Free Survival measured using patient records at the data cutoff (15.1.2025)
2. Overall Survival measured using patient records at the data cutoff (15.1.2025)

Key secondary outcome(s)

Completion date

15/01/2025

Eligibility

Key inclusion criteria

1. Women aged 18 years to 75 years
2. Histologically confirmed advanced epithelial ovarian cancer
3. Presence of peritoneal metastases
4. Suboptimal primary cytoreductive surgery with residual disease greater than 1 cm
5. No extraperitoneal metastases
6. No malignant pleural effusion
7. No parenchymal organ metastases
8. Eastern Cooperative Oncology Group (ECOG) performance status not equal to 4
9. No synchronous malignancies
10. No receipt of neoadjuvant chemotherapy

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

75 years

Sex

Female

Total final enrolment

190

Key exclusion criteria

1. Severe concomitant somatic, mental, and other pathology in a stage of exacerbation or decompensation
2. Cachexia with body mass index less than or equal to 16.0 kg/m²
3. Eastern Cooperative Oncology Group (ECOG) performance status 3 or 4
4. Pregnancy and lactation
5. Presence of extra abdominal metastases
6. Presence of a tumour of another localisation, meaning a primary multiple synchronous or metachronous process, except for metachronous neoplasms detected 2 or more years ago and in remission at the time of inclusion
7. Severe adhesions in the abdominal cavity when it is not possible to separate the adhesional conglomerate and achieve complete haemostasis, including cases where an adequate laparoscopic approach cannot be performed
8. Any other clinical condition that, in the opinion of the researcher, may interfere with the safe implementation of the protocol
9. Patient refusal to continue participating in the study at any stage

Date of first enrolment

01/08/2020

Date of final enrolment

31/12/2022

Locations**Countries of recruitment**

Russian Federation

Sponsor information**Organisation**

Moscow Regional Oncological Dispensary

Funder(s)

Funder type

Funder Name

Moscow Regional Oncological Dispensary

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------------------------|---------|--------------|------------|----------------|-----------------|
| Protocol file | | 09/04/2021 | 09/03/2026 | No | No |