An Indian Multicentric, Open Label, Prospective Phase IV Study of Bevacizumab in the Front Line Management of Advanced/Metastatic Epithelial Ovarian Cancer, Fallopian Tube Cancer or Primary Peritoneal Cancer in Real-Life Clinical Practice

First published: 10/09/2013

Last updated: 26/05/2026

Study Finalised

Administrative details

EU PAS number

EUPAS3724

Study ID

40367

DARWIN EU® study

No

Study countries

India

Study description

This is a Phase IV, single-arm, open-label, prospective, interventional, multicenter study of bevacizumab (Avastin) in real-life clinical setting. This study plans to enroll 100 subjects at approximately 20 sites across India.

Study status

Finalised

Research institutions and networks

Institutions

F. Hoffmann-La Roche

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 20 centres are involved in the study

Contact details

Study institution contact

Trial Information Support Line TISL

global.clinical_trial_registry@roche.com

Study contact

global.clinical_trial_registry@roche.com

Primary lead investigator

Vaibhav Watts

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/11/2012

Actual: 01/11/2012

Study start date

Planned: 28/11/2018

Actual: 05/12/2018

Data analysis start date

Actual: 18/06/2025

Date of final study report

Planned: 31/10/2025

Actual: 06/02/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Hoffmann-La Roche (Roche Products (India) Pvt, Ltd)

Study protocol

ML28446-Protocol v2_Redacted.pdf (326.54 KB)

ML28446-Protocol v3_Redacted.pdf (1020.87 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Non-EU RMP only

Other study registration identification numbers and links

ML28446

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Clinical trial

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

This is a Phase IV, single-arm, open-label, prospective, interventional, multicenter study.

Main study objective:

This multicenter, prospective, interventional study will evaluate the safety and efficacy of Avastin (bevacizumab) when added to standard chemotherapy (carboplatin and paclitaxel) in routine clinical practice in patients with advanced/metastatic epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer.

Study Design

Clinical trial regulatory scope

Post-authorisation interventional clinical trial

Clinical trial phase

Therapeutic use (Phase IV)

Clinical trial randomisation

Non-randomised clinical trial

Clinical trial types

Single-arm trial

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

AVASTIN

Study drug International non-proprietary name (INN) or common name

BEVACIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L01FG01) bevacizumab

bevacizumab

Medical condition to be studied

Fallopian tube cancer

Ovarian epithelial cancer metastatic

Peritoneal carcinoma metastatic

Population studied

Short description of the study population

Patients must meet the following criteria for study entry:

• Female subjects ≥18 years of age

• Subjects willing and able to give informed consent

• Subjects who are prescribed to receive bevacizumab for advanced/metastatic epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer (FIGO Stage lllb, lllc and lV) according to the routine clinical practice.

• Women of childbearing potential must agree to use adequate contraception (per institutional standard of care) during treatment and until 6 months after the last administration of bevacizumab.

Subjects who meet any of the following criteria will be excluded from study entry:

• There is no specific exclusion criteria for this study and subjects who are considered not eligible to receive bevacizumab for advanced/metastatic epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer (FIGO Stage IIIb, IIIc and IV) according to the local prescribing information will not be enrolled in the study.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Special population of interest

Women of childbearing potential using contraception

Estimated number of subjects

100

Study design details

Setting

13 center(s) in India

Interventions

The investigational medicinal product (IMP) for this study was Bevacizumab. The non-investigational therapies administered concurrently were Paclitaxel and Carboplatin. During the treatment phase, patients received Bevacizumab in combination with Paclitaxel and Carboplatin chemotherapy followed by Bevacizumab monotherapy.

Bevacizumab 15 mg/kg was administered intravenously every 3 weeks for five cycles concurrently with six cycles of standard chemotherapy (Paclitaxel and Carboplatin). Thereafter, patients continued to receive Bevacizumab 15 mg/kg every 3 weeks as a single agent for up to 16 additional cycles or until disease progression or death, whichever occurred earlier. A total of 21 cycles of Bevacizumab were planned in this study.

Paclitaxel and Carboplatin were administered according to locally approved prescribing information. All dose modifications, interruptions, and discontinuations were managed as per protocol and local label recommendations, with corresponding documentation in the eCRF. Medication

errors or overdoses, along with any related adverse events, were reported according to pharmacovigilance procedures.

Outcomes

• The incidence of AEs and SAEs
• Progression free survival (PFS)
• Overall survival (OS)
• Overall response rates (Complete response (CR)+ Partial response (PR))
• Clinical benefit response rates (CR+PR+ Stable disease(SD))

Data analysis plan

All efforts will be made to regularly follow up patients to calculate Progression Free survival (PFS) and Overall Survival (OS). Kaplan-Meier procedure will be used to estimate the median PFS and OS for total as well as ECOG PS 0 and ECOG PS 1-2 at baseline. Log rank test will be used to compare the median survival time between subjects with ECOG PS 0 and ECOG PS 1-2 at baseline. The overall response rate (CR + PR) will be summarized using number and percentage along with two-sided 95% Pearson-Clopper confidence interval. Similarly, the Clinical Benefit Response rate (CR + PR + SD) will be summarized using number and percentage along with the two-sided 95% Pearson-Clopper confidence interval. All statistical tests will be done at 5% level of significance. All patients with at least one follow up evaluation available would be evaluated for efficacy.

Summary results

• Treatment with bevacizumab plus standard chemotherapy followed by bevacizumab monotherapy demonstrated favorable overall survival (OS) and durable disease control in Indian patients with advanced/metastatic ovarian, fallopian tube, or primary peritoneal cancer.
• Median OS was not reached, and median PFS was approximately 24 months,

consistent with the known efficacy profile of bevacizumab in this indication.
• The safety profile of bevacizumab was manageable and predictable, with most adverse events (AEs) of low to moderate intensity.
• Serious or treatment-limiting toxicities were infrequent, and the incidence of Grade ≥3 and serious AEs was within the expected range for bevacizumab-treated populations.
• PFS outcomes in Indian patients were consistent with those observed in pivotal global trials and real-world studies.
• The toxicity profile mirrored the established global experience, with no new concerns identified in the Indian clinical setting.
• The study provides important local evidence supporting the integration of bevacizumab into front-line therapy for advanced/metastatic ovarian cancer in India.
• The results reinforce the favorable risk-benefit profile of bevacizumab when patients are appropriately selected and toxicities proactively managed.
• In conclusion, this Phase IV study met its regulatory objective, confirming that bevacizumab is both effective and safe in Indian patients with advanced/metastatic ovarian cancer and supports its role as a standard component of front-line therapy in this population.

Documents

Study report

ML28446-Final CSR Synopsis_Redacted.pdf (254.43 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Clinical trial

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No