ForPatients
by Roche

Fallopian Tube CancerPrimary Peritoneal CancerOvarian Cancer

A Study of the Efficacy and Safety of Bevacizumab in Chinese Women With Newly Diagnosed, Previously Untreated Stage III or Stage IV Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer.

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT03635489 YO40268

The clinical trial information herein is sourced from public registries such as ClinicalTrials.gov, EuClinicalTrials.eu, and ISRCTN.com. Additional patient-friendly (lay) content has been prepared by Roche to support understanding.

Official Title:

A Phase III Trial of Carboplatin and Paclitaxel Plus Placebo Versus Carboplatin Paclitaxel Plus Concurrent and Extended Bevacizumab in Chinese Women With Newly Diagnosed, Previously Untreated, Stage III or Stage IV Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

Trial Summary:

This multicenter, double-blind, 2-arm, randomized study will evaluate the efficacy and safety of bevacizumab plus paclitaxel and caboplatin compared with placebo plus paclitaxel and caboplatin in Chinese participants with newly diagnosed, previously untreated Stage III or Stage IV epithelial ovarian, fallopian tube, or primary peritoneal cancer. Participants whose disease has not progressed after six cycles of paclitaxel and carboplatin with either bevacizumab or placebo will continue treatment with either bevacizumab or placebo until disease progression, unacceptable toxicity, or a maximum of 22 cycles, whichever occurs first.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT03635489 YO40268
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Female	# 18 Years	No

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Inclusion Criteria:

- Participants receiving a histologic diagnosis of epithelial ovarian cancer (EOC), peritoneal primary carcinoma, or fallopian tube cancer.
- Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2.
- Life expectancy of at least 12 weeks.
- Adequate hematological, liver, renal and neurologic functions.
- For participants who receive therapeutic anticoagulation: stable anticoagulant regimen.
- Enrollment between 1 and 12 weeks after initial surgery is performed for the combined purpose of diagnosis, staging, and cytoreduction

Exclusion Criteria:

- Current diagnosis of borderline epithelial ovarian tumor or recurrent invasive epithelial ovarian, primary peritoneal, or fallopian tube cancer treated with surgery only.
- Prior radiotherapy to any portion of the abdominal cavity or pelvis.
- Prior chemotherapy for any abdominal or pelvic tumor, including neoadjuvant chemotherapy for ovarian, primary peritoneal, or fallopian tube cancer.
- Any prior targeted therapy (including, but not limited to, vaccines, antibodies, or tyrosine kinase inhibitors) or hormonal therapy for management of their epithelial ovarian or peritoneal primary cancer.
- Synchronous primary endometrial cancer.
- Have a prior history of primary endometrial cancer, except: Stage not greater than Stage IB; no more than superficial myometrial invasion, without vascular or lymphatic invasion; no poorly differentiated subtypes, including papillary serous, clear cell, or other International Federation of Gynecological Oncologists (FIGO) Grade 3 lesions.
- Cancer present within the last 5 years with the exception of non-melanoma-related skin cancers and other specific malignancies or whose previous cancer treatment contraindicates study treatment.
- Active hepatitis B virus (HBV) infection (chronic or acute) or active hepatitis C virus (HCV) infection.
- Serious non-healing wounds, ulcers, or bone fractures.
- Patients with clinically significant cardiovascular disease.
- Have known hypersensitivity to Chinese hamster ovary cell products or other recombinant human or humanized antibodies.
- Have known sensitivity to any component of paclitaxel.
- Undergo major surgical procedure within 28 days prior to randomization or anticipated during the course of the study.
- Have core biopsy or other minor surgical procedures within 7 days prior to the first dose of bevacizumab/placebo.
- History or evidence of thrombotic disorders within the last 6 months prior to enrollment.

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