

Belova: A non-interventional study to collect data on the safety and efficacy of frontline bevacizumab treatment in Figo Stage IV Ovarian Cancer patients ≥ 70 (BELOVA)

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Study

Finalised

Administrative details

EU PAS number

EUPAS13849

Study ID

35793

DARWIN EU® study

No

Study countries

 Belgium

Study description

This is a multi-center, non-interventional, post-authorization study to collect safety and efficacy data on the use of bevacizumab in ovarian cancer patients ≥ 70 years. Dosing and treatment duration are at the discretion of the investigator in accordance with the local labeling and reimbursement. Patients will be followed from start of bevacizumab treatment until progression or death from any cause, whichever comes first. The study will be open for recruitment for 3 years, then a follow-up period until the last patient has had disease progression or died, whichever comes first.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 20 centres are involved in the study

Contact details

Study institution contact

Julie Dewilde global.clinical_trial_registry@roche.com

Study contact

global.clinical_trial_registry@roche.com

Primary lead investigator

Julie Dewilde

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 25/02/2014

Study start date

Actual: 23/04/2015

Date of final study report

Actual: 04/06/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Roche

Study protocol

[ML29515_Protocol.pdf](#) (697.36 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

ML29515

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The purpose of this study is to evaluate the safety and efficacy in the frontline treatment of ovarian cancer in a wider selection of patients ≥ 70 years old in a routine clinical practice in Belgium. Bevacizumab will be used as described in the summary of product characteristics, in combination with carboplatin/paclitaxel followed by bevacizumab as maintenance.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Post-authorization study, Prescription event monitoring

Study drug and medical condition

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

BEVACIZUMAB

Medical condition to be studied

Ovarian cancer

Population studied

Short description of the study population

Elderly patients aged ≥ 70 y, for whom it has been decided to administer frontline treatment for FIGO stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer with bevacizumab in combination with chemotherapy according to standard of care and in line with the current summary of product characteristics (SPC)/local labeling. Patients should not have any contraindication to bevacizumab therapy as per the local label and are eligible for observation in this cohort if the following applies: Written informed consent where local regulations allow or require it within up to 4 weeks after commencing treatment. Each patient will undergo comprehensive geriatric assessment (CGA) at the start and a limited CGA during treatment, and the treatment pattern and safety profile of each patient will be followed-up until progressive disease. Patients must meet the following criteria for study entry:

1. Initially diagnosed with frontline stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer
2. aged ≥ 70 years
3. have signed the written informed consent and received a copy.
4. No treatment with any other investigational agent within 28 days or 2 investigational agent half-lives (whichever is longer) prior to enrolment in this study.

Patients who meet any of the following criteria will be excluded from study entry: Contraindications, warnings and precautions for use as specified in the bevacizumab SmPC.

Age groups

- Adults (65 to < 75 years)
 - Adults (75 to < 85 years)
 - Adults (85 years and over)
-

Special population of interest

Other

Special population of interest, other

Ovarian cancer patients

Estimated number of subjects

100

Study design details

Outcomes

Safety and tolerability of bevacizumab in the frontline treatment of elderly ovarian cancer patients, To describe:

- Demographic characteristics and medical history of the elderly population receiving bevacizumab
- Clinical Efficacy/progression free survival: start time of bevacizumab until progression or death
- Objective Response Rate
- Comprehensive Geriatric Assessments evolution
- Dosage, schedule of bevacizumab and combined chemotherapies for the treatment of elderly ovarian cancer patients

Data analysis plan

Statistical analyses will be performed primarily for descriptive and estimation purposes. Unless otherwise specified, all statistical hypotheses will be tested at the 5% significance level against two-sided alternatives, and corresponding 95% confidence intervals will be reported as appropriate. The incidence of related AEs and SAEs will be summarized according to the primary system-organ class (SOC) and within each SOC, by the Medical Dictionary for Regulatory Activities (MedDRA) preferred term. Rates and proportions will be associated with a 95% confidence interval according to 'Agresti-Coull' method (95% CI). Kaplan-Meier estimates and Kaplan-Meier Curve will be provided for

time-to-event variables (PFS). If possible, the median survival time will be reported with its 95% confidence interval based on the nonparametric Brookmeyer and Crowley method.

Documents

Study results

[ML29515_FinalCSR_Synopsis_8June2020_Redacted.pdf](#) (727.41 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)

[Other](#)

Data sources (types), other

Prospective patient-based data collection

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