AN OBSERVATIONAL STUDY OF AVASTIN® (BEVACIZUMAB) AS FIRST LINE THERAPY IN PATIENTS WITH ADVANCED OVARIAN CANCER (OSCAR 1)

First published: 24/07/2015

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Study Finalised

Administrative details

EU PAS number

EUPAS10394

Study ID

44667

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Multi-centre, observational (non-interventional) study to follow patients with aOC, who have received no previous treatment for advanced disease and are receiving or have received Avastin in combination with a standard of care first line chemotherapy regimen.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 30 centres are involved in the study

Contact details

Study institution contact

Leonardo Trani global.clinical_trial_registry@roche.com

Study contact

global.clinical_trial_registry@roche.com

Primary lead investigator

Leonardo Trani

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 18/03/2013

Study start date
Actual: 10/05/2013

Date of final study report
Actual: 15/06/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Roche

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

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

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To obtain ‘real world’ data from routine UK clinical practice for Avastin combined with chemotherapy in the first line treatment of advanced (FIGO stages IIIB, IIIC and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer (i.e. advanced ovarian cancer, aOC) and clinically relevant subgroups.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Drug interaction study

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

(L01XC07) bevacizumab

bevacizumab

Medical condition to be studied

Ovarian cancer

Population studied

Short description of the study population

Patients with advanced ovarian cancer who have received no previous treatment for advanced disease and are receiving or have received Avastin in combination with a standard of care first line chemotherapy regimen.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- 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

Patients with ovarian cancer

Estimated number of subjects

300

Study design details

Outcomes

- The incidence of all adverse events - Clinical Efficacy, as measured by progression free survival, after all subjects have been followed for a minimum of 12 months, -Response rate and overall survival-To describe:a) the key demographic characteristics and medical history of the population receiving Avastin for first line treatment of aOC in the UKb)dosage, schedule, timing and reasons for commencing and discontinuing treatment with Avastin.c)the dosage and schedule of chemotherapies used in combination with Avastin-To assess quality of life (QoL)

Data analysis plan

There are no predefined hypotheses regarding the primary and secondary objectives of the study. The primary objectives are to characterise the adverse event profiles observed in routine UK clinical practice as well as estimate PFS. Primary and secondary safety, demographic, treatment and outcome data will be summarised using descriptive statistics and 95% confidence intervals where appropriate.Time to PFS & OS data will be analysed using Kaplan-Meier methods. If data permit and assumptions hold, the effect of baseline stage of disease, time of Avastin dosing compared to time of chemotherapy, surgery and age on PFS & OS will be assessed using the Cox proportional hazards model. Other variables may also be explored.

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, Patients' medical records

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