An Observastional study of Avastin (Bevacizumab) in combination with chemotherapy for treatment of metastatic or locally advanced and unresectable colorectal cancer and locally advanced or metastatic non-small cell lung cancer (excluding predominant squamous cell histology) (ARIES)

First published: 28/09/2012

Last updated: 28/09/2012

Study Ongoing

Administrative details

EU PAS number

EUPAS3004

Study ID

3005

DARWIN EU® study

No

Study countries

United States

Study description

This is an observational study designed to follow patients with metastatic or locally advanced and unresectable CRC, locally advanced or metastatic NSCLC (excluding predominant squamous histology) who are receiving Avastin in combination with first-line chemotherapy. Second-line metastatic CRC patients are also eligible. Patients who started their Avastin containing therapy <3 months prior to enrollment are eligible.

Study status

Ongoing

Research institutions and networks

Institutions

Genentech

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Institution | Other

Contact details

Study institution contact

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Study contact

dalal.darshan@gene.com

Primary lead investigator

Darshan Dalal

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 05/09/2006

Study start date

Actual: 10/11/2006

Date of final study report

Planned: 31/01/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Genentech, Inc.

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Main study objective:

This is an observational study designed to evaluate the effectiveness and safety of patients with metastatic or locally advanced and unresectable CRC, locally advanced or metastatic NSCLC (excluding predominant squamous histology) who are receiving Avastin in combination with first-line chemotherapy. Second-line metastatic CRC patients are also eligible.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

AVASTIN

Medical condition to be studied

Colorectal cancer

Non-small cell lung cancer

Population studied

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)

Estimated number of subjects

4.000

Study design details

Outcomes

Effectiveness outcome measures (which include progression-free survival, response rate, overall survival)Safety outcome measures

Data analysis plan

Patient demographics and baseline characteristics will be described using summary statistics. Effectiveness and safety outcomes will be summarized overall (safety only), by tumor type (CRC and NSCLC), and by class of

chemotherapy.The effectiveness analyses for each indication will include Kaplan-Meier estimates of median PFS and overall survival (OS) and presented with 95% confidence intervals (CIs). Multivariable Cox proportional hazard regression models, adjusting for baseline covariates will also be performed. For CRC patients, PFS will be summarized separately for first-line and second-line patients.For safety analyses, descriptive summaries on protocol-specified BV-associated adverse events (AEs) over the entire follow-up will be presented. Incidence proportions and their exact 95% confidence intervals will be reported.

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