AN OBSERVATIONAL STUDY OF AVASTIN® (BEVACIZUMAB) IN COMBINATION WITH CHEMOTHERAPY FOR TREATMENT OF FIRST LINE METASTATIC COLORECTAL ADENOCARCINOMA (ACORN)

First published: 21/07/2015

Last updated: 21/07/2015

Study Ongoing

Administrative details

EU PAS number

EUPAS10344

Study ID

10345

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

STUDY OF BEVACIZUMAB IN COMBINATION WITH CHEMOTHERAPY DESIGNED TO FOLLOW PATIENTS WITH METASTATIC COLORECTAL ADENOCARCINOMA

Study status

Ongoing

Contact details

Study institution contact

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Study contact

leonardo.trani@roche.com

Primary lead investigator

Leonardo Trani

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/09/2011

Study start date

Actual: 06/07/2012

Date of final study report

Planned: 31/08/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Roche

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To assess the outcomes and the safety of Avastin® and first line chemotherapy regimens for metastatic colorectal cancer in a real world setting in England/the UK and to assess actual day to day disease and patient management.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Drug interaction study

Study drug and medical condition

Name of medicine

AVASTIN

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

BEVACIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L01XC07) bevacizumab

bevacizumab

Additional medical condition(s)

METASTATIC COLORECTAL ADENOCARCINOMA

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

700

Study design details

Outcomes

To obtain real world data of Avastin® combined with various chemotherapy regimens used for the treatment of first line metastatic colorectal cancer in the United Kingdom (UK) as assessed by:- The incidence of all serious adverse events and Grade 3-5 Avastin® related adverse events- Outcomes, as measured by progression-free survival, and duration of survival. -Via capture of all AEs -To describe regimens used in combination with Avastin® -To describe dosage, schedule, duration and reason for discontinuation of treatment with Avastin®-To describe the characteristics of populations receiving Avastin® -To explore deviations from Avastin® SmPC.-To describe the treatment paths for mCRC after 1st line treatment - To assess quality of life (QoL) d

Data analysis plan

There is no predefined hypothesis regarding the magnitude of the outcome variables of any regimen or the frequency or severity of adverse events.Safety and outcomes will be analysed using standard statistical methods for cohort studies for the overall study population and by concomitant first-linechemotherapy for metastatic colorectal cancer.Clinical outcomes will be evaluated and reviewed after 700 patients have been enrolled.

Data management

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