OPTIMIS - Outcomes of HCC patients treated with TACE followed or not followed by sorafenib and the influence of timing to initiate sorafenib

First published: 22/08/2013

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/26404

EU PAS number

EUPAS4564

Study ID

26404

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Brazil
- [ ] Canada
- [ ] China
- [ ] Egypt
- [ ] France
- [ ] Greece
- [ ] Hungary
- [ ] India
- [ ] Indonesia
- [ ] Japan
- [ ] Kazakhstan
- [ ] Korea, Republic of
- [ ] Mexico
- [ ] Netherlands
- [ ] Pakistan
- [ ] Russian Federation
- [ ] Singapore
- [ ] Slovakia
- [ ] Sweden
- [ ] Switzerland
- [ ] Taiwan
- [ ] Thailand
- [ ] Türkiye
- [ ] Viet Nam

Study description

This study will collect data of patients who are treated with TACE followed by sorafenib for hepatocellular carcinoma (HCC) or patients without Sorafenib after

TACE. In contrast to a prior observational study on sorafenib (GIDEON study), where pre-treatment with TACE was documented retrospectively, this study will collect more detailed information about the TACE treatment and the status of a patient when treatment with sorafenib is started.

Study status

Finalised

Research institutions and networks

Institutions

Bayer AG

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 25 centres are involved in the study

Contact details

Study institution contact

Bayer Clinical Trials Contact Bayer AG

Study contact

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Primary lead investigator

Bayer Clinical Trials Contact Bayer AG

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 05/12/2012

Actual: 05/12/2012

Study start date
Planned: 01/09/2013

Actual: 28/10/2013

Date of final study report
Planned: 30/06/2018

Actual: 07/06/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

OPTIMIS_PRO.pdf(1.86 MB)

OPTIMIS_PRO_v3_2015-09-04 FINAL.pdf(2.17 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The primary objective of this study is the comparison of two cohorts of hepatocellular carcinoma patients regarding overall survival (OS) from time of TACE non-eligibility. The two cohorts of special interest are defined based on the investigators' treatment decisions (i.e. patients with early start of Sorafenib treatment vs. patients without early start of Sorafenib treatment).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

NEXAVAR

Anatomical Therapeutic Chemical (ATC) code

(L01XE05) sorafenib

sorafenib

Medical condition to be studied

Hepatocellular carcinoma

Population studied

Short description of the study population

Patient with a diagnosis of unresectable Hepatocellular carcinoma (HCC).

Patients having following criteria were included:

- Patients with histologically/cytologically documented or radiographically diagnosed HCC. Radiographic diagnosis needs typical findings of HCC by radiographic method i.e. on multidimensional dynamic CT, CT hepatic arteriography (CTHA)/CT arterial portography (CTAP) or MRI.
- Patients with BCLC stage B or higher.
- Patients in whom a decision to treat with TACE has been made at time of study enrollment. Patients that have received one TACE in the past also can be enrolled, if the TACE was done at the same site and all required data about such previous TACEs are available. TACE includes both conventional TACE with lipidiol (or similar agents) and chemotherapeutic agent(s) and TACE with DC Beads® excluding TAE without chemotherapeutic agent.
- Patients with unresectable HCC (incurable with curative treatments including resection or ablation or not eligible for resection or local ablation)
- Patients must have signed an informed consent form
- Patients must have a life expectancy of at least 8 weeks

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

Hepatic impaired

Estimated number of subjects

1670

Study design details

Outcomes

Overall survival, defined as time (in days) from time of TACE non-eligibility to death due to any cause. Patients lost to follow-up or alive at the end of the study will be censored at the last date known to be alive. 1) Overall survival from initial TACE2) Progression-free survival from initial TACE3) Time to progression from initial TACE4) Tumor response according to mRECIST criteria5) Duration of treatment6) Number of patients with TEAEs (treatment emergent adverse events)For more secondary outcome measures please visit https://clinicaltrials.gov/ct2/show/NCT01933945

Data analysis plan

In general, statistical analyses will be of explorative and descriptive nature. Analyses will be performed for the total study population (overall analysis) and separately for the two patient cohorts of special interest, as appropriate. The primary efficacy endpoint is Overall Survival (OS). It is defined in this study as the time period from documented TACE non-eligibility to death due to any cause. For the two cohorts of special interest, Kaplan-Meier (KM) estimates for OS will be displayed. Furthermore, these two cohorts will be compared regarding overall survival using a Cox proportional hazards model. Where applicable, the propensity score approach will be applied in order to compare the two cohorts.

Documents

Study results

16560_EU PAS_Abstract_2018-10-10.pdf(227.73 KB)

Study report

16560 OPTIMIS_Report Addendum_v1.0_20181015_Redacted.pdf(1.1 MB)

16560 OPTIMIS_Report_v1.0_20180529_Redacted.pdf(2.77 MB)

Study, other information

16560 OPTIMIS_Report_v1.0_20180529_Redacted.pdf(2.77 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Medical records, routine measurements (e.g. tumor assessment), patients, other physicians

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

Unknown