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: 23/04/2024

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 institution 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 and secondary data collection

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

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Name of medicine
Nexavar

Anatomical Therapeutic Chemical (ATC) code
100000096735
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