Breast Cancer Treatment with Afinitor® (Everolimus) and Exemestane for HR+ Women (BRAWO)

First published: 16/04/2015

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS9462

Study ID

27127

DARWIN EU® study

No

Study countries

☐ Germany

Study description

BRAWO is a German, non-interventional study with a planned enrollment of 3,000 patients with HR+ advanced breast cancer receiving Everolimus+Exemestane according to the approved label.Main objectives of the BRAWO study are to extend knowledge in the following areas• Efficacy and the impact of physical activity on efficacy and quality of life in routine clinical care• Prophylaxis and management of stomatitis• Sequence of therapy and drug utilization when EVE+EXE is used in routine clinical care

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Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 400 centres are involved in the study

Contact details

Study institution contact

Novaratis Clinical Disclosure Office

trialandresults.registries@novartis.com

Study contact

trialandresults.registries@novartis.com

Primary lead investigator

Novaratis Clinical Disclosure Office

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/06/2012

Actual: 20/06/2012

Study start date

Planned: 01/10/2012

Actual: 12/10/2012

Data analysis start date

Planned: 08/06/2017

Actual: 29/12/2017

Date of interim report, if expected

Planned: 08/06/2015

Date of final study report

Planned: 31/12/2018

Actual: 16/11/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis

Study protocol

Protocol_final_BRAWO_CRAD001JDE53_Amendment 6 20151011_Redacted.pdf
(421.26 KB)

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

CRAD001JDE53

Methodological aspects

Study type

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The aim of this NIS is to acquire information from routine care• on the impact of physical activity on efficacy and quality of life, • on prophylaxis and management of stomatitis in routine clinical practice• on the sequence of treatmentin the treatment of patients with advanced or metastatic HR+ breast cancer who are treated on-label with Afinitor® und exemestane. AEs will be documented.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational Study

Study drug and medical condition

Name of medicine

AFINITOR

Medical condition to be studied

Breast cancer metastatic

Population studied

Short description of the study population

Postmenopausal women with advanced breast cancer previously treated with a nonsteroidal aromatase inhibitor and currently being treated with Afinitor® in accordance with routine practice and the Summary of Product Characteristics.

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

Breast Cancer metastatic patients

Estimated number of subjects

3000

Study design details

Outcomes

Primary Observation Parameters: Efficacy of combination of Afinitor® and exemestane in routine use and in relation to intensity of physical activity. Quality of life and physical activityDrug use and treatment sequenceStomatitis managementDocumentation of adverse events

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Data analysis plan

Variables measured to be analysed using epidemiology methods with primary use of descriptive statistical methods. If inferential statistical methods are used their results are considered to be purely descriptive. In this exploratory context, no alpha adjustments in multiple statistical comparisons are made.Variables reaching at least interval level will be presented in tabular form including their sample values (no of valid and missing values, min, max, 5th and 95% percentile, first and third quartile, median, mean, standard deviation). For variables at nominal and ordinal level, distribution of the absolute and relative frequencies will be indicated.For adverse events, incidences will be reported based on the patient population included and incidence density (number of events/sum of person times in years) according to the MedDRA system organ class and preferred term for adverse events. Times of events and survival time analyses will be analysed using the Kaplan-Meier methodology.

Documents

Study results

2018-11-16_CSR_BRAWO Final Report Redacted.pdf(1.09 MB)

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

Unknown