Health Care Professional survey on understanding of key risk minimisation measures related to interstitial lung disease (ILD) / pneumonitis with Trastuzumab Deruxtecan treatment

First published: 24/03/2022

Last updated: 27/05/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/46368

EU PAS number

EUPAS46367

Study ID

46368

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

Study description

Interstitial lung disease (ILD) and/or pneumonitis have been identified as important risks for patients treated with Trastuzumab Deruxtecan, and fatal outcomes have been observed. To prevent / minimize the occurrence of severe ILD/pneumonitis, the Marketing Authorization Holder proposed additional risk minimisation measures (aRMM) for ILD/ pneumonitis and developed educational material. A prescriber survey will be performed in the EU Member States where Trastuzumab Deruxtecan is marketed to evaluate effectiveness of the taken key risk minimisation measures for ILD/ pneumonitis. The aim of this study is to evaluate the effectiveness of Trastuzumab Deruxtecan’s risk minimisation measures for the important identified risk of ILD/pneumonitis by assessing their correct implementation among physicians expected to prescribe Trastuzumab Deruxtecan. Physicians’ knowledge and understanding of the educational material will be evaluated.

Study status

Finalised

Research institutions and networks

Institutions

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Primary lead investigator

Birgit Ehlken

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/01/2021

Actual: 17/06/2021

Study start date

Planned: 01/03/2022

Actual: 28/03/2022

Date of final study report
Planned: 30/06/2024

Actual: 26/06/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Daiichi Sankyo Europe GmbH

Study protocol

DSE_T-DXd_HCP Survey_Protocol_v1.0_20Dec2021_blackened.pdf(463.16 KB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Study design:

This is a cross-sectional, multi-national survey conducted among physicians who are prescribers
or potential prescribers of T-DXd in a selection of European countries where T-DXd is marketed.

Main study objective:

To assess physicians’ awareness, knowledge, and implementation of additional risk minimisation measures related to the risk, early detection, diagnosis and management of interstitial lung disease (ILD)/pneumonitis.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Name of medicine

ENHERTU

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

TRASTUZUMAB DERUXTECAN

Anatomical Therapeutic Chemical (ATC) code

(L01FD04) trastuzumab deruxtecan

trastuzumab deruxtecan

Medical condition to be studied

Breast cancer

Interstitial lung disease

Pneumonitis

Population studied

Short description of the study population

The population to be surveyed in the selected countries comprised physicians who were prescribers
or potential prescribers of T-DXd.

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

0

Study design details

Setting

The survey was conducted among office and hospital-based physicians in European countries
approximately 12 months after the distribution of EM for T-DXd.

Outcomes

The primary outcome of the aRMMs for T-DXd will be evaluated as effective if all of the following success criteria are met (1.-3.): 1. Proportion of physicians being aware of the important identified risk of ILD/pneumonitis, 2. Proportion of physicians knowledgeable about the important risk of ILD/pneumonitis, 3. Proportion of physicians answering the implementation questions correctly. Physicians' awareness of ILD/pneumonitis risk and its related minimisation measures, awareness of having received the education material, measure physicians' knowledge on the requirement for treatment modifications in case of suspected ILD/pneumonitis, assess whether physicians implement the measure (addressing the recommended talking points, distribution of patient alert card).

Data analysis plan

The statistical results of the physicians' survey data will be presented in one report, by country and combined. In addition, selected analyses will be stratified by physicians' prescribing status (prescriber vs. potential prescriber) and, if applicable, by specialty. It is aimed to consider weighting of results with respect to country and physician specialty to account for under- or overrepresentation of participants. The unweighted and weighted results for parameters related to study objectives will be presented. Data will be analysed descriptively. Continuous variables will be presented by their number (of valid cases), mean, standard deviation, median, first and third quartiles (Q1, Q3), minimum, and maximum. Categorical variables will be tabulated with absolute and relative frequency per category. Percentages will be calculated over the number of

observations with available (non-missing) data. Confidence intervals (CIs) of 95% will be calculated for weighted results as appropriate.

Documents

Study report

EUPAS46367_Report Abstract_May 2024.pdf(168.84 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Physician survey

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