Non-interventional post-marketing safety study (PMSS) to collect information on hepatic function disorders among Japanese patients with radically unresectable or metastatic renal cell carcinoma treated with pembrolizumab in combination with axitinib (MK-3475-A97)

First published: 07/04/2020

Last updated: 23/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48486

EU PAS number

EUPAS34319

Study ID

48486

DARWIN EU® study

No

Study countries

☐ Japan

Study description

The aim of this study is to collect information on hepatic disorders including clinical events and/or laboratory elevations with or without hepatic dysfunction in Japanese participants with radically unresectable or metastatic renal cell carcinoma (RCC) treated with pembrolizumab in combination with axitinib, and to describe treatment and resolution of these adverse events (AEs) in real-world clinical practice.

Study status

Finalised

Research institutions and networks

Institutions

Merck & Co.

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Merck Investigational Site Japan

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Study contact

ClinicalTrialsDisclosure@merck.com

Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 05/11/2019

Study start date

Planned: 31/07/2020

Actual: 17/06/2020

Data analysis start date

Planned: 31/05/2023

Actual: 26/04/2023

Date of final study report

Planned: 11/07/2024

Actual: 08/07/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme LLC

Study protocol

MK-3475-A97-00-v1-prot_final-redaction.pdf(8.78 MB)

MK-3475-A97-04-v1-Protocol_final redaction.pdf(1.87 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

Among the overall population of Japanese participants with radically unresectable or metastatic RCC who receive treatment with pembrolizumab in combination with axitinib, to describe the proportion of participants with hepatic disorders, including clinical events and/or laboratory elevations with or without hepatic dysfunction.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

INLYTA

KEYTRUDA

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

AXITINIB

PEMBROLIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L01EK01) axitinib

axitinib

(L01XC18) pembrolizumab

pembrolizumab

Medical condition to be studied

Renal cell carcinoma

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

200

Study design details

Outcomes

Proportion of participants with hepatic adverse events (HAEs, overall, serious and grade 3 or higher), including clinical events and/or laboratory elevations with or without hepatic dysfunction, (Overall) Baseline data, % discontinuing

treatment due to HAE, % with treatment interruption, % with dose reduction, time to discontinuation, interruption, resumption, and dose reduction, (participants with HAE) Baseline data, % with resolved HAE, % using steroids/other treatment, time to HAE onset, HAE summary. Subgroup analysis for HAEs will be performed (overall, serious, and >=grade 3)

Data analysis plan

Analyses will be of an explorative and descriptive nature. There is no formal hypothesis testing. Descriptive statistics will be reported including measures of central tendency and dispersion for continuous variables and frequency and percentages for categorical scale variables. Comparison of characteristics in subgroups will be performed using Chi-square test or Fisher's exact test for categorical/binary variables, and Student's t-test for continuous data. Other test statistics may be used, as relevant, depending on the data distributions and normality assumptions.

Documents

Study report

pa97mk3475-final report-jun-2024_final-redaction.pdf(750.15 KB)

Data management

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

No