

# 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

### EU PAS number

EUPAS34319

### Study ID

48486

### DARWIN EU® study

No

## Study countries

☐ Japan

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## 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.

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## Study status

Finalised

# Research institutions and networks

## Institutions

[Merck & Co.](#)

**First published:** 01/02/2024

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**Institution**

[Merck Investigational Site Japan](#)

## Contact details

**Study institution contact**

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Study contact

[ClinicalTrialsDisclosure@merck.com](mailto: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

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**Study start date**

Planned: 31/07/2020

Actual: 17/06/2020

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**Data analysis start date**

Planned: 31/05/2023

Actual: 26/04/2023

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**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

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### **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

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**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

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

AXITINIB

PEMBROLIZUMAB

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**Anatomical Therapeutic Chemical (ATC) code**

(L01EK01) axitinib

axitinib

(L01XC18) pembrolizumab

pembrolizumab

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### **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)

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### **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  $\geq$  grade 3)

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### **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](#)

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## **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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No