Non-interventional cohort registry study to assess characteristics and management of patients with Merkel Cell Carcinoma in Germany (MCC-TRIM)

First published: 28/08/2018

Last updated: 20/01/2025

Study Finalised

Administrative details

EU PAS number

EUPAS25338

Study ID

34181

DARWIN EU® study

No

Study countries

☐ Germany

Study description

This is a 5-year non-interventional (observational), longitudinal, multi-site cohort registry study focusing on various epidemiological and clinical aspects to be assessed in patients diagnosed with MCC in Germany. The design is an open cohort study design, with dynamic, renewed sampling, allowing for each eligible patient to have the same probability to be included throughout the inclusion period.

Study status

Finalised

Research institutions and networks

Institutions

Merck Healthcare KGaA

Germany

First published: 26/02/2024

Last updated: 26/02/2024

Institution

Contact details

Study institution contact

Communication Center Merck KGaA
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Study contact

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Primary lead investigator

Communication Center Merck KGaA

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 21/08/2017

Study start date

Planned: 01/04/2019

Actual: 29/04/2019

Date of final study report

Planned: 31/12/2024

Actual: 27/11/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck KGaA

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

Enlarge ADO MCC Registry by collecting additional data on treatment patterns, comorbidities, concomitant treatments, effectiveness and safety outcomes, HRU and biomarker Information.

This study aims to identify and describe population of MCC patients, their treatment and outcomes in a real-world settings in Germany.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Additional medical condition(s)

Merkel cell carcinoma

Population studied

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

Immunocompromised

Estimated number of subjects

1000

Study design details

Outcomes

In patients diagnosed with MCC in Germany

• Patient and tumor characteristics

• Background prevalence rates
• MCC-related treatments for all types and lines of therapy since initial diagnosis of MCC
• Relevant common comorbidities in patients with metastatic stage disease
• Concomitant medications
• Disease outcomes by means of response and survival analyses
• Safety events of interest

Data analysis plan

All statistical analysis will be done using SAS version 9.4 or higher. For categorical variables, summary tabulations of number and percentage within each category (with a category for missing data) of parameter will be presented. For continuous variables, mean, median, standard deviation, minimum and maximum values will be given. All time-to-event analyses will be performed by using Kaplan-Meier methods including calculation of median survival times and 95% confidence intervals (CIs).
Safety analysis will mainly involve assessment of incidence rates (e.g. fatal and nonfatal ADRs, rate of immune-related ADRs).
In addition, as this is an open cohort, accumulation of evidence will continue over the study duration. Data will be analyzed every 6 months as information from more patients is accumulated over the 5-year study period.
The study sponsor will also be able to perform ad hoc queries using the cohort data throughout the duration of the study period of 5 years.

Documents

Study report

ms100070_0031-csr_Redacted.pdf(1.94 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)

Disease registry

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