An International, Multi-Centre, Retrospective Study to Describe Treatment Pathways, Outcomes, And Resource Use in Patients with Multiple Myeloma (INTEGRATE)

First published: 30/01/2018

Last updated: 16/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS21846

Study ID

46405

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Australia

- [ ] China
- [ ] Colombia
- [ ] Hong Kong
- [ ] Korea, Republic of
- [ ] Mexico
- [ ] Russian Federation
- [ ] Saudi Arabia
- [ ] Singapore
- [ ] South Africa
- [ ] Taiwan
- [ ] Türkiye

Study description

The purpose of this study is to describe time to next treatment at each line of therapy in participants receiving frontline treatment for newly diagnosed Multiple Myeloma (NDMM), Cohort 1, and in participants with relapsed or refractory MM (RRMM), Cohort 2.

Study status

Finalised

Research institutions and networks

Institutions

Takeda

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 70 centres are involved in the study

Contact details

Study institution contact

Study Director Takeda trialdisclosures@Takeda.com

Study contact

trialdisclosures@Takeda.com

Primary lead investigator

Andrew Spencer

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/03/2018

Actual: 03/02/2017

Study start date

Planned: 30/03/2018

Actual: 21/03/2018

Data analysis start date
Planned: 20/03/2021

Actual: 30/03/2021

Date of final study report
Planned: 24/11/2021

Actual: 10/12/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

NDMM5002-Protocol-v1-Redacted.pdf(1.04 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The purpose of this study is to describe time to next treatment at each line of therapy in participants receiving frontline treatment for newly diagnosed Multiple Myeloma (NDMM), Cohort 1, and in participants with relapsed or refractory MM (RRMM), Cohort 2.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Review of medical records

Study drug and medical condition

Medical condition to be studied

Plasma cell myeloma

Population studied

Short description of the study population

Adult patients newly diagnosed with MM (NDMM) who have received frontline treatment with chemotherapy (Cohort 1) and patients with a diagnosis of RRMM.

Inclusion criteria

• Patients who have newly diagnosed symptomatic MM (Cohort 1) or presented with RRMM (Cohort 2) between 01st January 2010 and 31st December 2011 (inclusive).

• Patients who have completed at least one full line of treatment.

• Age ≥ 18 years at first diagnosis of MM (Cohort 1) or at diagnosis of RRMM (Cohort 2).

• Alive or deceased.

• Patient provides written informed consent for study data collection (as required by local regulations).

Exclusion criteria

• Patients for whom the minimum study dataset (Table 3) is unavailable from their hospital medical records.

• Patients with smouldering myeloma.

• Patients with monoclonal gammopathy of unknown significance (MGUS).

• Patients enrolled in a clinical trial of an investigational medicinal product during the observation period.

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

Multiple Myeloma patients

Estimated number of subjects

2600

Study design details

Outcomes

The primary outcome measre will be time to next treatment (TTNT) defined for Cohort 1 as the time from initiation of first treatment for MM and for Cohort 2 as the time from initiation of first treatment following presentation with RRMM, to date of next treatment or death, censored at date of data collection. The secondary endpoints will be patient characteristics, treatment pathways, clinical outcomes & adverse events and resource use and costs.

Data analysis plan

Descriptive analyses will be conducted to describe patient demographics and clinical characteristics, treatment patterns, clinical outcomes, healthcare resource use and costs. Key categorical endpoints will be summarised using

number and percentage in each category. Key continuous endpoints will be summarised using summary statistics of mean and standard deviation, median and interquartile range. Key time to event endpoints will be summarised in terms of total number of events observed and proportion of participants who have died/progressed at a given milestone after accounting for censoring using Kaplan-Meier curves. In addition to descriptive analyses, multivariate analyses will be conducted if possible to adjust for differences in patient demographic, clinical, and treatment characteristics, as well as risk factors that will be conducted for key time to event analyses, when treatment subgroups will be compared within the RRMM or NDMM cohorts wherever possible.

Documents

Study results

NDMM5002_CSR_summary-Redacted.pdf(1.28 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Retrospective 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