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Description of the management and outcomes of patients with frontline transplant-eligible multiple myeloma in four European countries (France, Germany, Spain and Italy)

Submission date
15/11/2021

Recruitment status
No longer recruiting

Registration date
22/11/2021

Overall study status
Completed

Last Edited
22/11/2021

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to provide insights on the current standard of care for the management of patients with frontline transplant eligible (FLTE) multiple myeloma (MM) in four European countries (France, Germany, Italy, and Spain). It aims also to investigate changes in the use of the different treatments in these patients in recent years (2017 – 2019). Finally, the outcomes associated with each treatment will be described.

Who can participate?
Data from patients with multiple myeloma based on their medical records.

What does the study involve?
Data on the patients will be extracted from databases in France, Germany, Italy, and Spain.

What are the possible benefits and risks of participating?
There are no expected benefits or risks to the participants.

Where is the study run from?
Kantar Health (France)

When is the study starting and how long is it expected to run for?
June 2021 to August 2021

Who is funding the study:
Janssen EMEA (Belgium)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
PCSONC003873

Study information

Scientific Title
Real-world study of the management and outcomes of patients with frontline transplant-eligible multiple myeloma in four European countries (France, Germany, Spain and Italy)

Study objectives
Which treatment regimen is considered the current standard of care in the selected European countries (France, Germany, Spain, Italy) for the management of patients with frontline transplant eligible multiple myeloma (FLTE MM) and what has been the evolution of the use of the different regimens in recent years?

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study does not require ethics approval. As this is an observational study that uses data previously collected and does not impose any form of intervention, no formal Consent to Release Information form and no Institutional Review Board/Independent Ethics Committee (IRB /IEC) review were required.
Cancerology database French Q1 2020 edition was conducted as part of the commitment of the MR-004 reference methodology which covers the data processing and delivered by the French Data Protection Authority (CNIL) with the authorization number n°2204473 v0. Other Cancerology database editions (French 2021, German 2021, Italian 2020, Spanish 2020) were conducted under ISO 20252 quality standards that guarantee the anonymity of the respondents and of their responses.

Primary study design

Observational

Study design
Non-interventional cross-sectional retrospective observational database study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Frontline transplant-eligible multiple myeloma

Interventions
A non-interventional retrospective observational study will be conducted in France, Germany, Italy and Spain. Patients with a reported diagnosis of multiple myeloma (MM) and on ongoing active treatment will be extracted from the Cancerology MM database editions of each of those four countries (French 2020 & 2021, German 2021, Spanish 2020, and Italian 2020 editions). The Cancerology MM database includes fully anonymized real-world data, composed of serial chart reviews of patients with a diagnosis of MM and on ongoing active treatment.

Intervention Type
Drug

Phase
Not Applicable

Primary outcome(s)
Repartition of the treatments received by the patients with frontline transplant eligible multiple myeloma in induction, consolidation, and maintenance phases and evolution of the repartition by year from 2017 to 2019, extracted from the Cancerology MM database editions of those four countries (French 2020 & 2021, German 2021, Spanish 2020, and Italian 2020 editions) collected for the period from diagnosis to date of data collection.

Key secondary outcome(s)
1. Time from frontline induction to frontline stem cell transplantation extracted from the Cancerology MM database editions of those four countries (French 2020 & 2021, German 2021, Spanish 2020, and Italian 2020 editions) collected for the period from start of frontline induction to frontline stem cell transplantation.
2. Time to next treatment calculated as the duration from the date of initiation of first-line induction to the initiation of the second line of treatment extracted from the Cancerology MM database editions of those four countries (French 2020 & 2021, German 2021, Spanish 2020, and Italian 2020 editions) collected for the period from start of frontline induction to initiation of second line of treatment.
3. Best observed response defined as per standard International myeloma working group response criteria over each previous phase of treatment extracted from the Cancerology MM database editions of those four countries (French 2020 & 2021, German 2021, Spanish 2020, and Italian 2020 editions) collected for the period from diagnosis to date of data collection.
4. Time to best-observed response calculated as the duration from the date of initiation of frontline therapy to the most recent best-observed response date extracted from the Cancerology MM database editions of those four countries (French 2020 & 2021, German 2021, Spanish 2020, and Italian 2020 editions) collected for the period from diagnosis to date of data collection.

5. Duration of therapy calculated as the time from the start of a given treatment to the discontinuation of the same treatment for any reason extracted from the Cancerology MM database editions of those four countries (French 2020 & 2021, German 2021, Spanish 2020, and Italian 2020 editions) collected for the period from diagnosis to date of data collection.
6. Treatment-free interval calculated as the time from the discontinuation of first-line therapy to the initiation of second-line therapy extracted from the Cancerology MM database editions of those four countries (French 2020 & 2021, German 2021, Spanish 2020, and Italian 2020 editions) collected for the period from discontinuation of first-line therapy to initiation of second line of treatment.
7. Minimal residual disease based on physician clinical judgement extracted from the Cancerology MM database editions of those four countries (French 2020 & 2021, German 2021, Spanish 2020, and Italian 2020 editions collected for the period from diagnosis to date of data collection.

Completion date
31/08/2021

Eligibility

Key inclusion criteria
Study population 1 (ongoing FLTE MM population):
1. Being on an ongoing frontline therapy line
2. Being considered either fit for transplant at initial diagnosis, or planned on transplant while on frontline therapy, or having already been transplanted while on frontline therapy

Study population 2 (previous FLTE MM population):
1. Being on an ongoing relapse or refractory multiple myeloma therapy line
2. Having received a previous frontline therapy line
3. Being considered either fit for transplant at initial diagnosis, or having already been transplanted while on frontline therapy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
804

Key exclusion criteria
Study population 1 (ongoing FLTE MM population):
1. Receiving the ongoing frontline therapy as part of a randomized controlled trial or early access program

Study population 2 (previous FLTE MM population):
1. Having initiated the frontline induction prior to 2017

Date of first enrolment
01/01/2020

Date of final enrolment
20/07/2021

Locations

Countries of recruitment
France

Germany

Italy

Spain

Study participating centre
University hospitals, Cancer Centre/oncological reference centre, General/Non-university hospital, Private hospital/clinic
France
-

Sponsor information

Organisation
Kantar Health (France)

Funder(s)

Funder type
Industry

Funder Name
Janssen EMEA

Results and Publications

Individual participant data (IPD) sharing plan

The participant-level data are proprietary of Kantar Health and Kantar Health is not allowed to share them publicly. The data are stored on a secured server of Kantar Health.

IPD sharing plan summary

Not expected to be made available