An observational, multicenter, prospective, phase IV study evaluating cladribine tablets' effects on PROs and their correlation with clinical and biometric parameters using Health Technology in subjects with highly-active RMS at their first switch (CLADFIT-MS)

First published: 05/11/2021

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Study Ongoing

Administrative details

EU PAS number

EUPAS43893

Study ID

43894

DARWIN EU® study

No

Study countries

Italy

Study status

Ongoing

Research institutions and networks

Institutions

Merck Healthcare KGaA

Germany

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Institution

Contact details

Study institution contact

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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
Planned: 27/07/2020

Study start date
Planned: 30/04/2021

Actual: 12/05/2021

Data analysis start date
Planned: 31/01/2025

Actual: 11/03/2025

Date of final study report
Planned: 31/07/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck KGaA

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 type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

The aim of the study will be to evaluate the effect of cladribine tablets on patient-reported outcomes (PROs) and their correlation to disability in subjects with highly-active MS (multiple sclerosis) who started their first switch from a disease-modifying drug (DMD) to cladribine tablets as their first second-line treatment in clinical practice.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

MAVENCLAD

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

CLADRIBINE

Anatomical Therapeutic Chemical (ATC) code

(L04AA40) cladribine

cladribine

Medical condition to be studied

Multiple sclerosis

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)

Estimated number of subjects

215

Study design details

Outcomes

- To evaluate changes in self-assessed physical impact of highly-active MS in daily life after the switch to cladribine tablets,
- Changes in self-assessed psychological impact, general health, cognitive functions, anxiety and depression, employment status after switch
- Relationship between changes and evaluations from wearable trackers
- Self-assessment and correlation with evaluations from wearable trackers
- Annualized relapse rate Real-world pharmacoeconomic data
- Safety in real-world clinical practice

Data analysis plan

No formal statistical hypothesis will be tested.
Quantitative (continuous) variables will be summarized using descriptive statistics, i.e. number of subjects with non-missing value, no of subjects with missing value, mean, SD, median, min and max, and first and third quartile.
Qualitative (categorical) variables will be displayed as frequency counts and percentages (n,%). Due to longitudinal nature of data, some outcomes data may be missing.
Patterns and degrees of missingness will be summarized.
As primary and secondary outcomes are based on PRO data, this will include the no of items missing for each scale and percentage of computable scale scores.
Descriptive statistics on outcome data may be used to identify potential data outliers. If CIs are to be calculated, these will be 2-sided with confidence probability of 95%.
For continuous data, CIs for mean will be calculated assuming a normal distribution of data. CIs for binary outcomes will be presented using Clopper-Pearson method

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)

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