ANALYSIS OF TREATMENT PATTERNS WITH DISEASE MODIFYING THERAPIES (DMTs) AMONG PATIENTS WITH MULTIPLE SCLEROSIS

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48106

EU PAS number

EUPAS48105

Study ID

48106

DARWIN EU® study

No

Study countries

Italy

Study status

Planned

Research institutions and networks

Institutions

University of Pisa

First published: 01/02/2024

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Institution

Center for Public Health Research (CESP), University of Milan Bicocca

Italy

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Institution | Educational Institution | ENCePP partner

Contact details

Study institution contact

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Primary lead investigator

Ersilia Lucenteforte

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/03/2022

Study start date

Planned: 01/09/2022

Date of final study report

Planned: 31/07/2023

Sources of funding

- Other

More details on funding

University

Study protocol

Multiple_Sclerosis_treatment_DU_07_07_2022.pdf(1.79 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 type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

- To estimate the population-based yearly prevalence, incidence, and consumption of disease modifying therapies (DMTs), - To describe the treatment patterns of DMTs in Multiple sclerosis patients, - To estimate the impact of demographic and clinical characteristics on the relationship between DMTs specific exposure and treatment patterns (i.e. switches, interruptions, and

drug discontinuations)

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L03AB07) interferon beta-1a

interferon beta-1a

(L03AB08) interferon beta-1b

interferon beta-1b

(L03AX13) glatiramer acetate

glatiramer acetate

(L04AA31) teriflunomide

teriflunomide

(L04AX07) dimethyl fumarate

dimethyl fumarate

(L04AA27) fingolimod

fingolimod

(L04AA23) natalizumab

natalizumab

(L04AA36) ocrelizumab

ocrelizumab

(L04AA34) alemtuzumab

alemtuzumab

(L01BB04) 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

3000

Study design details

Outcomes

- Prevalence, incidence, and consumption of disease modifying therapies (DMTs) in the study period, - Treatment patterns during follow-up: continuers, discontinuers, interrupters, switchers and mixed users.

Data analysis plan

- Incidence, prevalence, and consumption of DMTs use will be estimated yearly during the study period. - Subjects will be grouped according to the first DMT dispensed in the study period. Then, each subject will be defined according to their treatment patterns observed during the follow-up. Finally, demographic,

and clinical characteristics at the index date, as well as treatment patterns observed during the follow-up, will be summarized through standard descriptive statistic for each drug group. - For each DMT new user, treatment patterns during the entire follow-up will be plotted by using the Sankey diagram. - Recurrent events models and time-varying variables will be used to estimate the impact of the demographic and clinical covariates on the relationship between DMTs specific exposure and study outcomes (discontinuation and switch/interruption). Results will be expressed as Hazard Ratio (HR) with 95% CI.

Data management

Data sources

Data source(s)

ARS Toscana

Data sources (types)

Administrative healthcare records (e.g., claims)

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