Definition and validation of algorithms for the identification of specific clinical markers of multiple sclerosis using SNDS data (DIONISOS)

First published: 12/07/2023

Last updated: 15/03/2024

Study Planned

Administrative details

EU PAS number

EUPAS104596

Study ID

104597

DARWIN EU® study

No

Study countries

☐ France

Study description

Multiple sclerosis (MS) is an incapacitating, progressive, chronic neurological disorder that involves a selective, chronic inflammation and demyelination of the central nervous system. The severity of the disease varies from mildly forms to severe disabilities within a few years. Relapsing-remitting MS forms (RRMS) are the most common, and are characterized by the presence of relapses without disability progression between relapses. A complex algorithm for identifying MS relapses has been developed using SNDS data SNDS, and has been validated within the database using the sequence of patient care consumption in the SNDS. This is an original method that would benefit from external validation using clinical data. In this context, a validation study comparing clinical data of MS patients registered in the OFSEP database between 2010 and 2019 linked to the SNDS via probabilistic matching will be performed. The main objective is to evaluate and improve the diagnostic performance of an MS relapse identification algorithm developed from SNDS data using OFSEP clinical data linked to SNDS data as an external data source. Secondary objectives are to: - Develop and validate an SNDS algorithm to identify the level of MS-related motor disability and its evolution, - Develop and validate an SNDS algorithm to identify the level of disability specific to sphincter impairment and its evolution.

Study status

Planned

Research institutions and networks

Institutions

University of Bordeaux

France

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Laure Carcaillon-Bentata

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 23/03/2023

Study start date

Planned: 15/09/2023

Date of final study report

Planned: 31/12/2023

Sources of funding

- Other

More details on funding

Health Data Hub

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:

Other

If ‘other’, further details on the scope of the study

Algorithms validation

Main study objective:

The main objective is to evaluate and improve the diagnostic performance of an MS relapse identification algorithm developed from SNDS data using OFSEP clinical data linked to SNDS data as an external data source.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

4500

Study design details

Data analysis plan

The statistical analysis will be performed using the SAS software (latest current version), following a detailed statistical analysis plan. The following analyses will be performed: - a description of patient selection, - a description of initial patient characteristics, - for each algorithm (relapses, motor disability, disability specific to sphincter impairment): an estimate of the algorithm's sensitivity and diagnostic performance

Data management

Data sources

Data source(s), other

SNDS database France, OFSEP database France

Data sources (types)

Administrative healthcare records (e.g., claims)

Other

Data sources (types), other

Exposure 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