Safety and Tolerability Evaluation Profile in RMS Patients Starting Rebif New Formulation (STEP)

First published: 18/10/2018

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Study Finalised

Administrative details

EU PAS number

EUPAS26126

Study ID

26127

DARWIN EU® study

No

Study countries

☐ Italy

Study description

STEP was an observational, non-interventional, post-authorization safety study (PASS), settled in Italy, to evaluate the long-term safety and tolerability of HSA-free Rebif formulation (22 and 44 mcg) in treatment naïve patients with RMS. Secondary objectives were to assess the incidence of anti-interferon beta antibody development both of the binding (BAB) and the neutralizing (NAB) type. Tertiary objective was the evaluation of HSA-free Rebif formulation biological activity by monitoring MxA mRNA biomarker, the efficacy by monitoring EDSS (Expanded Disability Status Scale), FSS (Fatigue Severity Scale) and Multiple Sclerosis Relapse, change in quality of life through the Multiple Sclerosis International Quality of Life (MusiQol) questionnaire and RebiSmart injection device satisfaction through the RebiSmart questionnaire.The study design planned 200 RMS (Relapsing Multiple Sclerosis) treatment naïve patients recruited from around 29 MS Centers throughout Italy.The study duration included an 18-months recruitment period and a 36-months observation period after the last patient enrolment. Each enrolled patient was observed for a 36-months period starting from the first HSA-free administration, except in case of dropout from the study.

Study status

Finalised

Research institutions and networks

Institutions

Centro Riferimento Regionale Sclerosi Multipla (CreSM)

Multiple centres: 29 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Antonio Bertolotto

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 24/09/2009

Study start date

Planned: 07/10/2009

Actual: 22/09/2015

Date of final study report

Planned: 13/10/2015

Actual: 13/10/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Serono S.p.A.

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

EMR 701068_517

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The main objective of this study is to evaluate the long-term safety and tolerability of HSA-free Rebif formulation (22 and 44 mcg) in treatment naïve patients with RMS.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Post-authorization safety study (PASS)

Study drug and medical condition

Name of medicine

REBIF

Medical condition to be studied

Multiple sclerosis

Population studied

Short description of the study population

Treatment naïve patients with Relapsing Multiple Sclerosis (RMS).

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Other

Special population of interest, other

Relapsing Multiple Sclerosis (RMS) patients

Estimated number of subjects

200

Study design details

Outcomes

The primary outcome variable was the proportion of patients with Adverse Drug Reactions (ADRs). An ADR was defined as any response to a medicinal product which was noxious and unintended and a causal relationship between a medicinal product and an adverse event was at least a reasonable possibility. Secondary outcomes:Proportion of patients with specific categories of ADRs.

Proportion of patients with BAB positivity. Proportion of patients with NAB positivity.Tertiary outcomes: MxA mRNA levels,EDSS score,FSS (Fatigue Severity Scale) score,MS Relapse incidence, MusiQoL questionnaire overall score, RebiSmart questionnaire score.

Data analysis plan

The statistical software SAS® (version 8.0 or later) was used to conduct the statistical analysis. The following data sets were used for analysis and presentation of the study data: • All-subjects-enrolled set (ASE) – all enrolled subjects • All-subjects-treated set (AST) – all subjects in the ASE who took at least one dose of HSA-free • Full-analysis set (FAS) – all subjects in the AST who had at least one valid postbaseline assessment of the efficacy/quality of life variables • Per-protocol set (PPS) – all subjects in the FAS who: - did not violate any inclusion criterion or exclusion criterion- had good compliance with the study treatment (≥80%) - did not have any other deviation that was considered relevant from the clinical/statistical point of view.

Data management

Data sources

Data sources (types)

Disease 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

Unknown