# 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.

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**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**

Antonio Bertolotto antonio.bertolotto@gmail.com

Study contact

antonio.bertolotto@gmail.com

**Primary lead investigator**

Antonio Bertolotto

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual: 24/09/2009

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**Study start date**

Planned: 07/10/2009

Actual: 22/09/2015

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**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

**Medicinal product name**

REBIF

**Medical condition to be studied**

Multiple sclerosis

# Population studied

**Short description of the study population**

Treatment naïve patients with Relapsing Multiple Sclerosis (RMS).

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**Age groups**

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

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**Special population of interest**

Other

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**Special population of interest, other**

Relapsing Multiple Sclerosis (RMS) patients

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**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.

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**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

## 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)**

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