Plegridy* (peginterferon β-1a) Real World Effectiveness and Safety Observational Program (POP)

Published: 05-10-2015
Last updated: 20-04-2024

This study will be conducted as a prospective, observational study of patients with relapsing forms of MS initiating treatment with Plegridy in routine clinical practice and patients who participated in Study 105MS302 or Study 105MS303. Enrolled...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system infections and inflammations
Study type	Observational invasive

Summary

ID

NL-OMON47245

Source
ToetsingOnline

Brief title
105MS401_The POP study

Condition

- Central nervous system infections and inflammations

Synonym
Multiple Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: IQVIA RDS Netherlands B.V.
Source(s) of monetary or material Support: sponsor of the study [Biogen]

Intervention

Keyword: observational, Plegridy, real world

Outcome measures

Primary outcome

Primary:

- Incidence proportion and incidence rates of SAEs

- Clinical no evidence of disease activity (NEDA) evaluated by the proportion of patients with no evidence of clinical disease activity (no relapses and no disability progression)

Please refer to the protocol, starting at page 26, chapter 6.2

Secondary outcome

Secondary endpoints:

- Prescription and utilization patterns evaluated by assessment of prescribed dosing frequency, duration of Plegridy use, and primary reason for discontinuation of Plegridy

- Relapse activity evaluated by:

o Annualized relapse rate

o Time to first relapse

o Proportion of patients with relapse

o Distribution of the number of relapses

- Disability progression measured by EDSS:

o Proportion of patients with sustained progression for at least six months

o Time to sustained disability progression for at least six months

- Incidence proportion and incidence rates of AEs, including but not limited to FLS, ISRs, and AEs (including laboratory abnormalities) leading to treatment discontinuation

- The impact of the severity of FLS on the ability to successfully manage symptoms via prophylaxis will be evaluated using the patient-reported FLS-VAS

-Changes in FLS assessment and FLS-VAS over time

- Changes in EuroQoL EQ-5D, 3-level (EQ-5D-3L) score over time

Treatment adherence as measured by changes in adherence over time as reported in the treatment adherence questionnaires

o In countries where pen/syringe collection is locally allowed, treatment adherence will also be assessed by the proportion of used auto-injector pens/pre-filled syringes of total prescribed

- Frequency of MS-related and non-MS-related physician visits, specialists* visits, use of physiotherapy, hospitalizations and lengths of stay, and emergency room/department visits

Please refer to the protocol, starting at page 26, chapter 6.2

Study description

Background summary

Despite recent approval of several new therapeutic agents for treatment of multiple sclerosis (MS), there continues to be a high unmet medical need in this patient population for effective therapies with an established safety profile that are convenient to use over a long time period. Observational studies are increasingly being used - across many therapeutic areas and chronic diseases, including MS - to study the long-term effects of medications and

interventions on broad patient populations under real-world conditions.
Interferon beta-1a (IFN β-1a) therapy has been successfully used as a disease-modifying therapy to demonstrated to be effective in delaying the progression of disability and in reducing the rate of treat patients with relapsing forms of MS for over 15 years. Plegridy* (peginterferon β-1a) has a longer half-life than IFN β-1a. As such, it has been shown to reduce the frequency of administration versus IFN β-1a, thereby increasing treatment convenience. Consequently, we expect that it will improve compliance while maintaining a safety and efficacy profile at least similar to IFN β-1a.
Findings from the pivotal Phase III study (Study 105MS301, 1-year) demonstrated that Plegridy administered at a dose of 125 µg via subcutaneous injection every two weeks is an effective treatment for relapsing forms of MS.
In the clinical trial, treatment with Plegridy has clinical relapses, but it has also been associated with flu-like symptoms (FLS, including muscle aches, fever, fatigue, and chills) and injection site reactions (ISRs), which are typical of IFN products. In clinical practice, pre- and post-injection treatment with acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs) for the FLS is common. However, the effects of Plegridy did not have a negative effect on patients* health-related quality of life (HRQoL) compared with placebo. There is a need to continue to collect long-term data to help optimize patient management and support continued access to Plegridy in the real-world setting.

Study objective

This study will be conducted as a prospective, observational study of patients with relapsing forms of MS initiating treatment with Plegridy in routine clinical practice and patients who participated in Study 105MS302 or Study 105MS303. Enrolled patients will be followed for a maximum of five years (regardless of treatment discontinuation) or until patient death, withdrawal, or the patient is considered lost to follow-up. Data will be collected from information routinely recorded in the medical record or prospectively collected by the Prescribing Physician. Patient-reported outcomes (PROs) will be completed by patients online (±four weeks of routine clinical visit) to allow for completion of the questionnaires outside the physician*s office.

Study design

This study will be conducted as a prospective, observational study of patients with relapsing forms of MS initiating
treatment with Plegridy in routine clinical practice and patients who participated in Study 105MS302 or Study 105MS303. Enrolled patients will be followed for a maximum of five years (regardless of treatment discontinuation) or until patient death, withdrawal, or the
patient is considered lost to follow-up. Data will be collected from information routinely recorded in the medical record or prospectively collected

by the Prescribing Physician. Patient-reported outcomes (PROs) will be completed by patients online (±four weeks of routine clinical visit) to allow for completion of the questionnaires outside the physician's office.

Study burden and risks

Not applicable, no expected risks for this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patient and or legal representative is willing and able to understand the purpose and risks of the study and provide signed and dated informed consent and authorization to use

protected health information (PHI) in accordance with national and local patient privacy regulations.
2. Patient with MS who has been newly prescribed Plegridy according to local label or patient who participated in Study 105MS302 or Study 105MS303.
3. Patient age 18 years or older.
4. Patient willing and able to complete PROs with minimal assistance.
Please refer to protocol page 30 chapter 8.1

Exclusion criteria

Patients will be excluded from study entry if the following exclusion criterion exists at the time enrollment.
1. Concurrent enrollment in any clinical trial of an investigational product. Participation in non-interventional study can be allowed as long as this participation does not interfere with this protocol or is likely to affect the subject*s ability to comply with the protocol.
Please refer to page 30 chapter 8.2

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-11-2015
Enrollment:	49
Type:	Actual

Ethics review

Approved WMO

Date:	05-10-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-06-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-11-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT02230969
CCMO	NL54283.100.15