Brimonidine Tartrate for the Treatment of Injection Related Erythema Associated with Sub-cutaneous Administration of Peginterferon beta-1a

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Primary ObjectivesTo evaluate the IRE intensity/color mitigation effect of a single administration of Brimonidine tartrate in comparison with a vehicle gel (placebo).Secondary ObjectiveTo evaluate the IRE intensity/color mitigation effect of a...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Administration site reactions
Study type	Interventional

Summary

ID

NL-OMON42363

Source
ToetsingOnline

Brief title
BRITE

Condition

- Administration site reactions
- Autoimmune disorders
- Skin vascular abnormalities

Synonym
erythema, redness of the skin

Research involving
Human

Sponsors and support

Primary sponsor: Biogen MA Inc.
Source(s) of monetary or material Support: Biogen MA Inc. financiert dit onderzoek.

Intervention

Keyword: Erythema, Mitigation, Multiple Sclerose, Plegridy injection

Outcome measures

Primary outcome

A change in either CEA or PSA scale measured as at least 1-grade improvement on CEA and/or at least 1-grade improvement on PSA scale assessed by the physician and patient, respectively, 6 hours after gel application, compared to the same measure before gel application.

Secondary outcome

A composite change in both CEA and PSA scale measured as at least 1-grade improvement on CEA and 1-grade improvement on PSA respectively; This composite endpoint is considered to be sensitive enough and directly correlated with patients* satisfaction therapy outcomes. CEA and PSA assessments will be performed before gel application, and then 6 hours after gel application at the physician*s office.

A composite change in both CEA and PSA scale measured as at least 2-grade improvement on CEA and 2-grade improvement on PSA;

Subject*s self-assessment of satisfaction with the overall appearance of their skin by using a Patient*s Assessment of Appearance (PAA) grading scale.

At least 2-grade change on CEA scale recorded 6 hours after gel application at

the site of erythema affected skin.

Study description

Background summary

PLEGRIDY (peginterferon *-1a) is a disease modifying therapy indicated to treat patients with relapsing forms of multiple sclerosis (RRMS). Pegylation of IFN *-1a has allowed, among other advantages, a longer half-life leading to less frequent dosing regimen compared to the original molecule which can translate in a better treatment experience for MS patients. During the Phase III pivotal PLEGRIDY trial in IFN treatment naïve patients, injection site erythema was the most common adverse event reported by patients in the active treatment arm (64%) over the course of 2 years. One possible Injection Site Reaction mitigation strategy is topical vasoconstriction at the injection site. On this basis, the vasoconstriction effect of Brimonidine tartrate might help alleviate the injections related erythema associated with sub-cutaneous administration of peginterferon beta-1a. A clinically meaningful reduction of the Injection-Related Erythema (IRE) is hypothesized to improve the patient*s treatment experience possibly leading to a positive impact on therapy adherence.

Study objective

Primary Objectives
To evaluate the IRE intensity/color mitigation effect of a single administration of Brimonidine tartrate in comparison with a vehicle gel (placebo).

Secondary Objective
To evaluate the IRE intensity/color mitigation effect of a single administration of brimonidine tartrate in comparison with a vehicle gel on a more stringent definition scale, in accordance with the primary endpoint of the original Brimonidine pivotal trials and patients* satisfaction with the overall appearance of their skin.

Study design

The BRITE study is a double blinded, self-controlled, cross-over Phase IV study to assess topical application of Brimonidine tartrate gel on mitigation of erythema severity in order to achieve an even better treatment experience with PLEGRIDY in patients who develop mild to moderate injection site erythema

according to the Clinician*s Erythema Assessment (CEA) and the Patient Self-Assessment (PSA). CEA and PSA are two 5-point scales specifically developed for the Brimonidine pivotal trial that assess the erythema severity on clinicians* and patients* judgment, respectively.

Intervention

Patients will be randomised after erythema has developed within 72 hours after post full dose Plegridy injection. During this visit the gel will be applied (either placebo or brimonidine tartrate) and the patients will complete the questionnaires pre-application and 6 hours post application.

Study burden and risks

The patient will have a maximum of three study specific visits. During the first visit Informed consent will be signed if the patient wants to participate and if the patient is eligible per protocol criteria. Also medical history will be collected and a dermatological exam will be performed. A maximum of 2 visits will take place after inclusion. During these visits the gel will be applied (placebo or brimonidine tartrate and vice versa) and the questionnaires will be completed pre gel application and 6 hours post-application.

Contacts

Public
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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- RRMS patients naive to treatment with SC interferon or oral and/or IV DMT for which PLEGRIDY is deemed necessary by the treating physician.
- 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.
- Patient age 18 years or older.
- Patient willing and able to complete PSA and PAA questionnaires with minimal assistance.
- Development of injection site erythema with a score of 2 or higher on the PSA or CEA scale (occurring after first or second full dose of PLEGRIDY).

Exclusion criteria

- 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.
- Patients with history of any clinically significant cardiac, endocrinologic, hematologic, hepatic, immunologic, metabolic, urologic, pulmonary, neurologic, dermatologic, psychiatric, and renal, or other major disease, as determined by the Investigator.
- Known allergy to any interferon or any component of PLEGRIDY (peginterferon beta-1a).
- Patients with hypersensitivity to Brimonidine topical gel.
- Patients with other skin disorders.
- History of previous treatment with Brimonidine tartrate (either eye drops or Mirvaso).
- History of drug or alcohol abuse (as defined by the Investigator) within 6 months prior to Day 1.
- Active bacterial or viral infection.
- Female subjects who are pregnant or currently breastfeeding.
- Inability to comply with study requirements.

Study design

Design

Study phase: 4

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-10-2015
Enrollment:	32
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Mirvaso
Generic name:	Brimonidine Tartrate
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	25-08-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	09-10-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	05-11-2015
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-12-2015
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
EudraCT	EUCTR2015-002159-89-NL
ClinicalTrials.gov	NCT0256811
CCMO	NL53602.100.15