An extension study to evaluate the long-term outcomes of subjects who received treatment for retinopathy of prematurity in Study 20090

Published: 10-07-2019
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This extension study aims to collect long-term data on safety and efficacy in a subject population treated for ROP with aflibercept and/or laser, and to contribute to the clarification of potential effects.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Retina, choroid and vitreous haemorrhages and vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON49661

Source
ToetsingOnline

Brief title
FIREFLEYE Next

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
retinopathy of prematurity, ROP

Research involving
Human

Sponsors and support

Primary sponsor: Bayer

Source(s) of monetary or material Support: Bayer A.G.

Intervention

Keyword: Aflibercept, EYLEA, FIREFLEYE Next, ROP

Outcome measures

Primary outcome

- Binocular best-corrected visual acuity in Snellen equivalent at 5 years of age.

- Proportion of subjects with ocular AEs and SAEs up to 5 years of age.

- Proportion of subjects with systemic AEs and SAEs up to 5 years of age.

Secondary outcome

- Proportion of subjects developing unfavorable ocular structural outcome at 1,3 and 5 years of age. Unfavorable ocular structural outcome include: retinal detachment, macular dragging, macular fold, retrolental opacity.

- Proportion of subjects with absence of active ROP at 1 year of age.

- Proportion of subjects with unfavorable structural outcomes at 1 year of age.

- Best-corrected visual acuity in each eye at 3 and 5 years of age.

- Refractive spherical equivalent in each eye at 3 and 5 years of age.

- Neurodevelopmental outcomes using standardized development tests (BSID-III, DAS-II, WPPSI-IV, VABS-II) at 2 and 5 years of age.

- Proportion of subjects with recurrence of ROP at 3 and 5 years of age.

- Proportion of subjects requiring treatment for ROP up to 5 years of age.

- Proportion of subjects requiring ophthalmological treatment up to 5 years of

age.

Study description

Background summary

The long-term effects of laser photocoagulation for the treatment of ROP is known, including irreversible loss of visual field and high myopia. The purpose of the current study is to primarily collect the missing data of the potential long-term effects after treatment with aflibercept and laser. Subjects will be followed to 5 years of age, which will enable a detailed assessment of visual function and overall development.

Study objective

This extension study aims to collect long-term data on safety and efficacy in a subject population treated for ROP with aflibercept and/or laser, and to contribute to the clarification of potential effects.

Study design

This is a Phase 3b, multi-center study to assess the long-term outcomes of subjects previously diagnosed with ROP who were treated in Study 20090. No study treatment is defined to be administered during this study. The study interventions being assessed were administered in Study 20090 (aflibercept and/or laser photocoagulation). Any potential non-study treatments are to be decided by the treating physician, according to local standards of care. The screening/baseline visit of Study 20275 can be conducted concomitantly with the Week 24 visit or the last follow-up visit of Study 20090, whichever is later, or at a later point between this date and before the subject is 13 months of chronological age. Additional visits will be scheduled at 40 wks and according to the subject*s yearly birthday (±1 month), with the last visit at the subject*s 5th birthday (±1 month).

Study burden and risks

Study participation includes routine physical, neurological, and ophthalmologic examinations that are generally accepted as standards of care. The follow-up planned in this study will be beneficial in assessing the long-term development of subjects who were treated with aflibercept and/or laser photocoagulation in Study 20090. Participation in the study involves approximately 7 visits in a time period of 5 years. Risks associated with ophthalmological examinations are low and are mainly related to pupil dilation (widening), including allergic reactions to eye drops and temporary blurred vision. Examinations including eye

examinations and physical exams, will be performed at specific visits as described in the protocol and the patient information and informed consent forms.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Subjects are eligible to be included in the study only if the following criteria apply: 1.Subject was treated in Study 20090, 2.Age less than 13 months of chronological age, 3.Signed informed consent from parent(s)/legally authorized representative(s) as described in Section 10.1.3 of the clinical trial protocol, which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in the protocol

Exclusion criteria

Subjects are excluded from the study if the following criterion applies:
Medical Conditions, 1. Subject has a condition preventing participation in the study, or performance of study procedures

Study design

Design

Study phase:	3
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-12-2020
Enrollment:	2
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	EYLEA
Generic name:	aflibercept
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	10-07-2019
Application type:	First submission

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	17-07-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	29-10-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	30-10-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	03-03-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-04-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-08-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	03-03-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO	

Date:	23-02-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-02-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2018-003180-54-NL
CCMO	NL69814.056.19