A 36 month observational study to describe the long-term efficacy and safety of ranibizumab 0.5 mg treatment in patients with visual impairment due to choroidalneovascularization (CNV) secondary to pathologic myopia (PM)

First published: 10/03/2015

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS8816

Study ID

35754

DARWIN EU® study

No

Study countries

- [ ] Canada
- [ ] Egypt
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Poland
- [ ] Portugal
- [ ] Russian Federation
- [ ] Spain
- [ ] Switzerland
- [ ] United Kingdom

Study description

This is a 36-month, 300-patient observational study to describe the long-term efficacy and safety of ranibizumab in patients with visual impairment due to CNV secondary to PM treated according to local regulations and standards of clinical practice. This study is a voluntary PASS.Patients with previous or concomitant treatment with verteporfin-PDT or previous laser are eligible for enrollment. Enrolled patients should not have received treatment with a systemic VEGF inhibitor for 90 days prior to enrollment, or an ocular VEGF inhibitor for 30 days prior to enrollment.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Institution

Multiple centres: 80 centres are involved in the study

Contact details

Study institution contact

Novartis Clinical Disclosure Office
Trialandresults.registry@novartis.com

Study contact

Trialandresults.registry@novartis.com

Primary lead investigator

Clinical Disclosure Office

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 13/08/2014

Actual: 13/08/2014

Study start date
Planned: 01/06/2015

Actual: 18/06/2015

Date of final study report
Planned: 30/06/2020

Actual: 24/03/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharma, AG

Study protocol

RFB002F2401-v00-protocol redacted.pdf(2.13 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Other study registration identification numbers and links

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To describe the long-term efficacy of ranibizumab as it is used in routine clinical practice for the treatment of visual impairment due to CNV secondary to PM. This will be determined by assessing the change in best corrected visual acuity (BCVA) from study entry throughout a 36 month observational period, in the primary eye designated for treatment.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational, multicenter, open label study

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

RANIBIZUMAB

Medical condition to be studied

Pathologic myopia

Population studied

Short description of the study population

300 male or female patients diagnosed with visual impairment due to choroidal neovascularization (CNV) secondary to pathologic myopia (PM) and intended to be treated with ranibizumab were planned to be entered into the study and to be observed for a period of 36 months.

In order to be included into the study, patients had to meet the following selection criteria:

1. be willing and able to sign an Informed Consent
2. be diagnosed with visual impairment due to CNV secondary to PM and be intended to be treated with ranibizumab
3. be ≥ 18 years old (adults per local regulations)
4. has not been treated with a systemic VEGF inhibitor for 90 days prior to

enrollment
5. has not been treated with an ocular VEGF inhibitor for 30 days prior to enrollment, or intravitreal/subTenons steroids for 90 days prior to enrollment
Pregnant women were not allowed to be included except if, in the opinion of the investigator, the expected benefit outweighted the potential risk to the fetus. Women of childbearing potential had to use an effective method of contraception. Breast-feeding was not recommended during the use of ranibizumab. The patient could have received previous treatment for CNV secondary to PM (e.g, vPDT, laser, anti-VGEF including ranibizumab).

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Pathologic myopia patients

Estimated number of subjects

300

Study design details

Outcomes

Change in best corrected visual acuity (BCVA) from study entry throughout a 36 month observational period, in the primary eye designated for treatment. 1 Ocular and systemic safety of ranibizumab 0.5 mg.2 Categorized change in BCVA over time, from study entry to month 36. 3 Efficacy by lesion subtype 4 Visual acuity outcomes in patients previously treated with vPDT or laser treatment.5 Visual acuity outcomes and safety in patients receiving combined treatment of vPDT and ranibizumab.

Data analysis plan

No hypotheses are planned to be testing for this single arm observational study. Descriptive statistics and time plots will be used to describe the change from baseline in BCVA throughout the trial. If there are sufficient data, subgroup analyses will be conducted to explore differences amongst patients receiving different treatments (separately for before and during the trial). Safety will be explored using treatment emerging adverse events.

Documents

Study results

rfb002f2401--study-report-body_3_Redacted.pdf(494.72 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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

No