Efetividade de Materiais Educacionais para Profissionais de Saúde e População geral Alvo enquanto Medidas Adicionais de Minimização de Risco para Vabysmo®, Eylea® e Lucentis® - O Estudo MARVEL

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Study Planned

Administrative details

EU PAS number

EUPAS106809

Study ID

106810

DARWIN EU® study

No

Study countries

☐ Portugal

Study description

Ophthalmological diseases affect all age groups and are increasingly prevalent. Pathologies such as age-related macular degeneration (AMD), diabetic macular edema (DME), retinal vein occlusion (RVO), and choroidal neovascularization (CNV) affect the posterior region of the eye, and have common treatment options available. The medicines Vabysmo®, Eylea® and Lucentis® are classified as Antineovascularization Agents and are used in the treatment of these ocular pathologies. Educational programs aim to adequately inform patients about the risks associated with the medicine, and as such their effectiveness must be guaranteed.

Study status

Planned

Research institutions and networks

Institutions

Association for Innovation and Biomedical Research on Light and Image (AIBILI)

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Institution

Contact details

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Primary lead investigator

Liseta Lemos

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/09/2023

Study start date
Planned: 15/09/2023

Data analysis start date
Planned: 31/10/2023

Date of final study report
Planned: 30/11/2023

Sources of funding

- Other

More details on funding

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Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The objective of the study is to evaluate the effectiveness of educational materials designed to healthcare professionals and patients used as additional risk minimisation measures for Vabysmo® (faricimab), Eylea® (aflibercept) and Lucentis® (ranibizumab).

Study Design

Non-interventional study design

Cohort

Population studied

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)

Estimated number of subjects

500

Study design details

Outcomes

For healthcare professionals and the general population target, evaluate: - Receiving and viewing educational materials used as additional risk minimisation measures for Vabysmo® (faricimab), Eylea® (aflibercept) and Lucentis® (ranibizumab). - The level of knowledge of the key messages described in the educational materials used as additional risk minimisation measures for Vabysmo® (faricimab), Eylea® (aflibercept) and Lucentis® (ranibizumab).

Data analysis plan

Descriptive statistics will be used. Frequency distributions with 95% confidence intervals (CI) will be calculated for all responses. The data will be stratified by target group: health care professionals and patients/caregivers and by medicine.

Data management

ENCePP Seal

Signed checklist for study protocols

ENCePPChecklistforStudyProtocols_preenchido.pdf(290.84 KB)

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