MULTICENTER PROSPECTIVE OBSERVATIONAL STUDY ON THE TREATMENT OF OPHTHALMIC INFLAMMATORY DISEASES NOT RESPONDING TO LOCAL STEROIDS WITH INTRAVITREAL TRIAMCINOLONE ACETONIDE

First published: 22/03/2018

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Study | Finalised

Administrative details

EU PAS number

EUPAS23281

Study ID

23282

DARWIN EU® study

No

Study countries

Italy

Study status

Finalised

Research institutions and networks

Institutions

Azienda Ospedaliera-Universitaria Policlinico Vittorio Emanuele Università degli Studi di Catania Clinica Oculistica

Ospedale “SS Annunziata” Chieti - Clinica Oftalmologica CATANIA, Azienda Ospedaliera Fatebenefratelli e Oftalmico - U.O. Oculistica CHIETI

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/09/2014

Actual: 18/09/2014

Study start date

Planned: 20/10/2014

Actual: 20/10/2014

Date of final study report

Planned: 22/03/2018

Actual: 22/03/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

SOOFT italia S.p.A.

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To evaluate the tolerability of intravitreal injections of an 8% suspension of triamcinolone acetonide (Taioftal®) on patients affected by diabetic macular oedema due to inflammatory aetiology of the diseases.

Study drug and medical condition

Medicinal product name, other

TAIOFTAL

Medical condition to be studied

Macular oedema

Population studied

Short description of the study population

Patients affected by diabetic macular oedema due to inflammatory aetiology of the diseases treated 8% suspension of triamcinolone acetonide (Taioftal®).

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

Patients with diabetic macular oedema

Estimated number of subjects

50

Study design details

Outcomes

Intraocular pressure measured by Goldmann applanationtonometry,• Cataract occurrence or worsening,• Vitreal reaction evaluated by slit lamp examination and/or OCTanalysis,• Ocular surface analysed by slit lamp,• Every other side effect to be reported in the CRF. macular thikness by OCT,visual acuity

Data analysis plan

This is an observational non-comparative study, then no formal samplesize estimate is needed. Previous studies on the treatment of diabeticmacular edema enrolled between 30 and 70 patients, regardless if theywere observational non-comparative or comparative clinical trials. Forthis reason, 50 patients can be considered a sample size large enough toinvestigate the above mentioned endpoints. This is even more trueconsidering that most of the patients will suffer from diabetic macularedema at both eyes. Analyzing each single eye, the sample size will beautomatically increased.Comparisons with baseline measurements will be performed. The resultswill be then compared with similar findings published in the literature.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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

Unknown