

Treatment of Clinically Significant diabetic Macular Edema: influence of Bevacizumab, Triamcinolone and the combination of both plus macular grid thermal laser Photocoagulation of subthreshold

Submission date 18/12/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 15/05/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 23/09/2021	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
FOM-RETINA 1

Study information

Scientific Title

Treatment of Clinically Significant diabetic Macular Edema: influence of Bevacizumab, Triamcinolone and the combination of both plus macular grid thermal laser Photocoagulation of subthreshold

Acronym

BTP-CSME

Study objectives

Clinically Significant Macular Edema (CSME) has no perfect treatment. Both grid photocoagulation and intraocular anti-angiogenic or corticosteroid substances have shown their utility. We want to determine the best combination to maintain/improve visual acuity and macular function.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval pending from the Comité Ético de Investigación Clínica (Clinical Research Ethics Committee).

Primary study design

Interventional

Study design

Prospective, randomised, single-centre, interventional trial.

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diabetic clinically significant diffuse macular edema

Interventions

Avastin group: intravitreal Bevacizumab 0.05 ml and then the same dose one and a half months later if edema is detected in Optical Coherence Tomography (OCT)

Triamcinolone group: intravitreal Triamcinolone 8 mg/0.1 ml and then the same dose three months later if edema is detected in OCT

Combination therapy group: Bevacizumab 0.05 ml followed by 8 mg/0.1 ml intravitreal triamcinolone seven days later, and the same dose three months later if needed (OCT detection)

Length of the treatment will be one year, then visual acuity will be evaluated, OCT performed and we will decide to interrupt or to continue if beneficial results can be expected.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Bevacizumab, triamcinolone

Primary outcome(s)

Visual acuity comparison

Key secondary outcome(s)

1. Macular visual field comparison
2. OCT variations of edema

Completion date

01/01/2008

Eligibility

Key inclusion criteria

1. Diabetic CSME not treated previously
2. Best Corrected Visual Acuity (BCVA) less than 20/40
3. Patient able to complete follow-up
4. Controlled diabetes

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

Key exclusion criteria

1. Other associated ocular pathology
2. Ocular surgery three months before the inclusion
3. Participating in other interventional studies

Date of first enrolment

01/01/2007

Date of final enrolment

01/01/2008

Locations

Countries of recruitment

Spain

Study participating centre
Fundación Oftalmológica del Mediterráneo
Valencia
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46015

Sponsor information

Organisation
Ophthalmological Foundation of the Mediterranean (Fundacion Oftalmologica del Mediterraneo)
(Spain)

Funder(s)

Funder type
Research organisation

Funder Name
Ophthalmological Foundation of the Mediterranean (Fundacion Oftalmologica del Mediterraneo)
(Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration