ISRCTN10939948 https://doi.org/10.1186/ISRCTN10939948

Treatment of Clinically Significative 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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 15/05/2007	**Overall study status** Completed	
Last Edited 23/09/2021	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Amparo Navea

Contact details
Fundación Oftalmológica del Mediterráneo
Bifurcación Pio Baroja-General Aviles s/n
Valencia
Spain
46015
-
navea_amp@gva.es

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
FOM-RETINA 1

Study information

Scientific Title
Treatment of Clinically Significative 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).

Study design
Prospective, randomised, single-centre, interventional trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Diabetic clinically significative 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 measure
Visual acuity comparison

Secondary outcome measures
1. Macular visual field comparison
2. OCT variations of edema

Overall study start date
01/01/2007

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

Age group
Not Specified

Sex
Both

Target number of participants

60

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
Spain
46015

Sponsor information

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

Sponsor details
Bifurcación Pio Baroja-General Aviles s/n
Valencia
Spain
46015
-
navea_amp@gva.es

Sponsor type
Research council

Website
http://www.fom.es/

Funder(s)

Funder type
Research organisation

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration