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Intravitreal versus subtenon triamcinolone acetonide for the treatment of diabetic cystoid macular oedema

Submission date 05/02/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/02/2008	**Overall study status** Completed	
Last Edited 15/04/2008	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Macular oedema is the main cause of loss of visual acuity in diabetic patients. It may occur at any stage of the retinal disorder and is the most common cause of sight reductions in these subjects.

In the oedema, the haemato-retinal barrier is damaged by an alteration in the tight junction between the retinal capillary endothelial cells and the pigmented epithelial cells with the consequent leakage of water and electrolytes in the retinal tissue.

The use of corticosteroids for the treatment of retinal oedema is linked to their capacity to inhibit the initial arachidonic acid cascade, to determine a down-regulation of the cytokines and to attenuate the tearing of the haemato-retinal barrier.

Hypothesis:
To assess the efficacy of the intravitreal (IVT) injection of triamcinolone acetonide (TA) as compared to posterior subtenon (SBT) capsule injection for the treatment of cystoid diabetic macular oedema.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Institutional Ethics Committee of the S. Orsola-Malpighi Hospital on the 12th September 2006 (ref: OFC06-01).

Study design
An interventional randomised double-blind study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Macular oedema

Interventions
For the IVT injection, the patient was placed supine and we performed a surface anaesthesia with topical 4% carbocaine followed by a preparation with 5% povidone iodine. A volume of 0.1 ml containing 4 mg preservative-free TA (Kenacort, Bristol-Myers Squibb, Sermoneta, Italy) was

injected through the inferotemporal pars-plana (4.0 mm posterior to the limbus) using a 30-gauge needle.

For the SBT injection, the patient was placed supine and after topical 0.4% oxybuprocaine surface anaesthesia we administered 0.5 ml of a 40 mg/ml peribulbar inferotemporal subtenon injection of preservative-free TA (Kenacort, Bristol-Myers Squibb, Sermoneta, Italy) with a 27-gauge needle.

The follow-up was of 6 months for all treatment arms.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Triamcinolone acetonide

Primary outcome measure
Visual acuity was assessed using the Early Treatment Diabetic Retinopathy Study (ETDRS) chart, measured every month until the end of follow-up.

Secondary outcome measures
Macular thickness was measured by optical coherence tomography (OCT), measured every month until the end of follow-up.

Overall study start date
03/02/2004

Completion date
18/10/2004

Eligibility

Key inclusion criteria
1. Patients aged between 61 and 74 years (mean 68.3), either sex
2. With type II diabetes mellitus
3. On insulin treatment
4. Presenting diffuse macular oedema without retinal-vitreous traction

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
28

Key exclusion criteria
1. History of focal/grid laser photocoagulation in the macula
2. Record of uveitis episodes
3. Previous ocular surgery, glaucoma and ocular hypertension

Date of first enrolment
03/02/2004

Date of final enrolment
18/10/2004

Locations

Countries of recruitment
Italy

Study participating centre
Via Massarenti, 9
Bologna
Italy
40100

Sponsor information

Organisation
St Orsola Malpighi University Hospital Bologna (Italy)

Sponsor details
Ophthalmology Service
Department of Surgery and Transplant
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Bologna
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Sponsor type
University/education

ROR
https://ror.org/00t4vnv68

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St Orsola Malpighi University Hospital Bologna (Italy)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	17/03/2008		Yes	No