

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

Submission date 05/02/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/02/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/04/2008	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

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
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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)

ROR

<https://ror.org/00t4vnnv68>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

St Orsola Malpighi University Hospital Bologna (Italy)

Results and Publications

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