Efficacy and safety of intravitreal injection of triamcinolone acetonide as treatment for diffuse diabetic macular edema

Evaluación de la eficacia y seguridad de la inyección intravítrea de acétónido de triamcinolona en el tratamiento del edema de mácula difuso del diabético

One of the first independent clinical trials of Spanish ophthalmology (1) was started in 2005. At that time and to this date, triamcinolone acetone intra-ocular injections are utilized without a sufficiently demonstrated scientific base, purely on the grounds of isolated clinical cases or small series. For this reason, the Thematic Network 03/13, led by Professor Sánchez Salorio, proposed the Carlos III Institute to carry out said trial. The following centers participated in the trial: Complutense and San Carlos Clinical Hospital of Madrid, Vall de Hebron hospital of Barcelona, Ophthalmological Institute of Alicante, University and Hospital of Murcia, INGO and University Hospital of Santiago de Compostela, University Clinic of Navarra and IOBA and Clinical Hospital of Valladolid under the coordination of IOBA as promoter of the trial.

The idea was to compare the efficiency of grid laser against a group of patient who were given the same treatment one month after a 4mg injection of triamcinolone taking advantage of the retinal thickness reduction it causes. The EUDRA number was requested (CT:2005-001385-14) and the project was registered in the trials base of the National Institute of Health (NCT:00309192).

On January 23, 2006, after the approval of the Spanish Medications Agency, the prospective, randomized and parallel trial began. And in early 2009 it was completed after overcoming a number of problems with the patience and perseverance of the researchers. Sixty percent of the scheduled patients were included (57 out of 98) and its main conclusions are the following:

– A greater retinal thickness reduction was observed in the triamcinolone group.
– No significant differences were found in visual acuity.
– After six months, there is 30% more cataracts in the triamcinolone group.

– In this group, 4 patients exhibited increased intra-ocular pressure and one required treatment, even though all were submitted to the provocation test with dexametasone before being accepted.
– No endophthalmitis or severe adverse effects have been observed.

In the light of this trial, continuing the use of this treatment for this type of patients (cystic edema and poor vision) is questionable. Accordingly, the new Thematic Network does not recommend its utilization.

In this period of time, additional research has been published, notably by the Diabetic Retinopathy Clinical Research Network (2) with 840 eyes. Its results indicate that after 2 years, laser is more effective and exhibits less adverse effects than 1mg or 4mg triamcinolone injections without preservatives.

Even though some papers state that its use should continue (3), the clarity of the work by the DRC.net establishes that intravitreous triamcinolone only produces a temporary improvement in diabetic macular edema but in the long term does not yield better functional results than laser, with the added drawback that it significantly increases complications.

In addition to the above conclusions, there are other highly positive experiences derived from this multi-centre trial which have encouraged other trials which are now in full swing. More importantly, Spanish ophthalmology has demonstrated it is able to cooperate in a network and complete its work, overcome all difficulties.

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REFERENCES