

R1 R2 R3 PG0 PG1 Estagiário Tecnólogo PIBIC

Last Name - Felberg

First Name - Sergio

Middle -

Service (sector)

Cornea and External Disease

Nº CEP

0910-03

Oral Pilocarpine for the treatment of dry eyes in patients with Sjögren syndrome

Sergio Felberg, Paulo E.C. Dantas and Elcio H. Sato

PURPOSE: To evaluate the efficacy, side effects and tolerability of oral pilocarpine for the treatment of ocular symptoms and signs in patients with Sjögren's syndrome (SS). **METHODS:** 32 patients with SS were included in this prospective, randomized, doubled-blind, placebo-controlled, crossover study. Patients were randomized according to a computer-generated schedule to receive 5 mg of oral pilocarpine hydrochloride or placebo tablets four times daily. Each treatment period lasted for 10 weeks, then the patient crossed over to the other study product after a 2-week washout period. Global evaluation and symptoms of dry eye were assessed by questionnaires (NEI-VFQ 25 and Ocular Surface Disease Index) and objective clinical assessments were performed using rose bengal staining, tear film break-up time (BUT), Schirmer I test (without anesthesia), Schirmer II test (with nasal stimulation), non-invasive break up time (NIBUT), fluorescein staining, tear ferning test, tear osmolarity and tear lysozyme activity. All the assessments were carried out at baseline and the end of each treatment period. The frequency and severity of adverse events occurring during the study were also recorded. **RESULTS:** Compared to placebo, significant differences were seen with pilocarpine 5 mg four times daily, in subjective symptoms, tear dynamics, condition of the corneoconjunctival epithelium, and global improvement rating. Patients taking oral pilocarpine had improvement in subjective global assessment of dry eyes, as was evaluated by improvement for responses to the OSDI and NEI-FVQ 25 questionnaires. Tear flow measured by Schirmer I and Schirmer II was increased in the pilocarpine group, furthermore, patients receiving oral pilocarpine also showed improvement measured by the rose bengal staining score, fluorescein staining score, BUT, NIBUT, tear osmolarity and tear lysozyme activity. The tear ferning patterns I and II, rarely observed during placebo phase, were more prevalent after the treatment with pilocarpine. Although adverse effects have been very frequently reported, the drug was well tolerated. The most common pilocarpine-related side effects were sweating but it was generally mild and tolerable. Others reported adverse events were urinary frequency, flushing, and chills. No serious drug-related adverse effect was found in this study.

CONCLUSIONS: Administration of 5mg pilocarpine tablets 4 times daily

(20mg/d) was well tolerated and produce improvement in symptoms and signs in patients with Sjogren's syndrome.