CASE STUDY

proderm
MEDICAL

KERATOCONJUNCTIVITIS SICCA

A phase IV clinical study on the ocular tolerability of a gel over 12 months

In this case study, we present an in-home-use test of a product for dry eye syndrome over a period of twelve months with two groups, one receiving the investigational product and the other group receiving a reference product to demonstrate non-inferiority. This study was performed as a full service trial, providing both site services and CRO support, including protocol development and regulatory submissions.

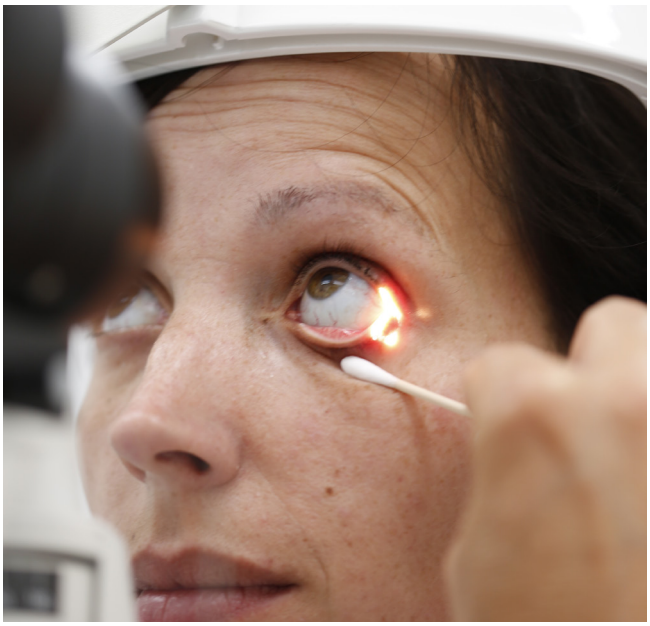
Study specifications:

- Randomized
- Double-blind
- Monocentric
- Phase IV
- IMP vs reference product
- Repeated ocular applications over 12 months
- 120 patients with keratoconjunctivitis sicca

Measuring ocular tolerability

As primary parameter, we collected subjective tolerability assessments by patients with sum scores of the parameters dryness, itching and discomfort after six weeks. Secondary parameters were, among others, the objective assessment of ocular irritation by an ophthalmologist and subjective tolerability assessment by patients covering different time points up to 12 months. This study was conducted as an in-home use test over 12 months.

Treatment of dry eyes syndrome



Our experienced ophthalmologist carefully checks for signs of ocular irritation

Running dry: Measuring tear film break up time

Another important parameter in this study was the objective assessment of eye dryness or tear film stability. The tear film breakup time (BUT) is a diagnostic test used to assess the stability of the tear film in patients. A tear film break up time of < 10 sec is considered the threshold for dry eye or sicca syndrome. To manually measure BUT, a substance called fluorescein is instilled into the subject's eye. After blinking 2-3 times, the subject then needs to keep their eyes open without blinking while looking into a slit lamp under a broad beam of cobalt blue illumination. The BUT is recorded as the number of seconds that elapse between the last blink and the appearance of the first dry spot in the tear film as measured by the ophthalmologist with a stopwatch.

Key challenges

For an eye tolerance study, the relatively long study duration demanded special attention to keep drop-out rates low so we recruited a high number of reliable subjects and kept regular contact through our contact center. We finished the study with only 15 dropouts.

Study milestones

129
patients screened

120
patients randomized

15
drop outs

1
year study duration

Results

Patients reported significantly less dry eye-related symptoms and our results clearly demonstrated non-inferiority compared to the reference product in the subjective tolerance assessment after 6 weeks. Also, patients in both groups showed higher break-up times, demonstrating better tear film stability. The test product is currently in the market as a safe and effective treatment for keratoconjunctivitis sicca.

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