Rexon-Eye device for the treatment of dry eye

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Scientific background

Dry eye disease is a highly prevalent and disabling disorder, which affects 9 million persons in the United States alone (1). Affected individuals can have considerable reduction in quality of life and suffer from decreased visual function, social and physical functioning and workplace productivity (2). Available treatments include administration of artificial tear substitutes, suppression of ocular inflammation and treatment targeted at improving meibomian gland function and eyelid hygiene. These treatments all have limited efficacy and dry eye remains a chronic and debilitating disease and an area of unmet medical need.

The Rexon Eye device (Resono Ophthalmic Inc., Trieste, Italy) is a new device based on QMR technology. Quantum Molecular Resonance (QMR) is a technique in which low-intensity, high-frequency electric currents are administered to a biological tissue through contact electrodes. The device applies stimulation to the epidermis of closed eyelids up to the lid margin by means of specially designed goggles. Previous studies have shown that it is relatively safe with high patient satisfaction (3). Preliminary studies have also shown it is effective for accelerate healing in chronic wounds and for treating symptoms of dry eye (4,5).

Possible harms and adverse events

One previous study reported no adverse events related to treatment (5). A second study reported adverse events related to the use of the Rexon device in three cases (3/25, 12%). Two patients showed mild cutaneous erythema following the first treatment and one patient generically felt uncomfortable during the treatment. Additional reported adverse events were anterior uveitis in one patient within the second month of treatment and one event of conjunctivitis within the second month of treatment. One patient suffered from a seasonal allergy during the last two weeks of treatment. The connection of these events to the treatment could not be ascertained (4).

Description of the proposed research

In this study, we aim to examine the efficacy of the Rexon eye device for the treatment of dry eye signs and symptoms in a randomized double-blind placebo-controlled fashion among a cohort of prospectively recruited patients with dry eye. The control group will receive similar application of treatment with the device goggles disconnected from the device, effectively receiving no treatment. The treatment will be performed by research assistants following thorough instruction by the manufacturing company representatives and/or provided material. Participant will be actively questioned on any harms or side effects in every meeting.

Outcomes will be assessed based on clinical signs (e.g. tear break up time, superficial punctate keratitis, meibomian gland dysfunction, Schirmer test). Symptoms of dry eye will be assessed by validated questionnaires on dry eye symptoms (OSDI).

Informed written consent will be obtained from all participants involved in the stud prior to enrolment. The goal of the study is to evaluate the Rexon device as a possible additional treatment option to patients with dry eye or to establish it has no added benefit.

Inclusion criteria:

- Patients above the age of 18 years

- Patients who are willing and able to consent and adhere to the research plan

- Patients diagnosed with dry eye

Exclusion criteria:

- Active infection of the eyelid or periorbital area

- Patients who are pregnant or lactating

- Patients under the age of 18

- Those scheduled for (<30 days) or immediately after (<30 days) ocular surgery (excluding cataract and eyelid surgery)

Methods

1) Recruitment of patients with dry eye, at risk for dry eye (e.g. post refractive surgery and post cataract surgery), meibomian gland dysfunction.

2) Randomization in a 1:1 ratio for treatment or control groups according to a pre-determined computer-generated randomized sequence.

3) Treatment or placebo treatment for one month weekly using the Rexon device by a research assistant.

4) Follow-up meeting assessing dry eye symptoms and clinical signs of dry eye.

5) Data analysis and report of outcomes.

Recruitment

We intend to recruit 25 patients in each group (total of 50 patients).

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Funding and conflict of interest

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