Trial Protocol

Title:

Efficacy and safety of Intense pulsed light therapy for dry eye caused by meibomian gland dysfunction: a randomised trial

Research subjects:

A total of 132 patients with MGD dry eye, who had been admitted from January 2018 to January 2020 to The Second Hospital of Shanxi Medical University, were selected as the research subjects.

Inclusion criteria:

(I) be aged 18 to 80 years old; (II) meet the diagnostic criteria of "eyelid gland dysfunction and dry eye" as per the "expert consensus on clinical diagnosis and treatment of dry eye" formulated by Ophthalmology Society of Chinese Medical Association (8); (III) have a lower lacrimal river height >0.1 mm, and a meibomian gland obstruction level 1–2; (IV) have monocular or binocular lesions; and (V) provide informed consent and sign an informed consent form.

Exclusion criteria:

(I) had experienced cute ocular surface inflammation and ocular trauma; (II) were being treated with steroidal and non-steroidal anti-inflammatory drugs and immunosuppressants; (III) had participated in other medical device trials or drug clinical trials within the last 3 months; (IV) was a woman with a severe organic disease or malignant tumor, was pregnant or had recently given birth; and/or (V) demonstrated poor compliance or provided incomplete information.

Grouping:

Patients were randomly divided into two groups on average (experimental group and control group).

Interventions

Experimental group: Patients were treated with IPL.

Control group: Patients were treated with a meibomian gland massage combined with a hot compress treatment.

Therapeutic effects

Observe and compare the treatment effect(effective, effective, ineffective) of two groups of patients.

Clinical features

The clinical symptoms of the two groups of patients were observed and compared. The meibomian gland number score, lacrimal duct height measurement, and Schirmer test were performed before treatment, 7 days after treatment, and 30 days after treatment.

Safety analysis

Observe and compare the Incidence of adverse events of two groups of patients.

Patient satisfaction evaluation

Observe and compare the patient satisfaction rate of two groups of patients.

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