Informed Consent

Efficacy and Safety of Different Hyaluronic Acid Tear Substitutes Formulations in Evaporative Dry Eye: A Randomized, Single-Blind, Comparative Study

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TITLE OF STUDY

Efficacy and Safety of Different Hyaluronic Acid Tear Substitutes Formulations in Evaporative Dry Eye: A Randomized, Single-Blind, Comparative Study

PRINCIPAL INVESTIGATOR

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PURPOSE OF STUDY

You are being asked to take part in a research study. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. Please read the following information carefully. Please ask the researcher if there is anything that is not clear or if you need more information.

The objective of the study is to compare the efficacy and safety of different hyaluronic acid tear substitutes formulations in patients with evaporative dry eye. For this purpose, a randomized, single-blind clinical trial has been designed

STUDY PROCEDURES

Eligible participants were randomized to receive either 0.20% cross-linked HA tear substitute (Off Health S.p.a., Firenze, Italy) or 0.15% HA tear substitute (Thea Pharma S.p.a., Milan, Italy).

Patients were instructed to instill 1 drop of 0.20% cross-linked HA tear substitute or 0.15% HA tear substitute into each eye 3 times per day for 3 months. Both tear substitutes are transparent, with no special smell and the bottles were identical in appearance such that patients and investigators were masked to treatment assignment.

RISKS

Cross-linked HA and HA-based tear substitutes have components that have been shown to be safe and well tolerated in humans. However, when instilling the tear substitute you may feel some of the following side effects: itching, stinging and eye irritation that may last a few minutes. You may decline to answer any or all questions and you may terminate your involvement at any time if you choose.

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BENEFITS

The main benefits of this treatment will be the improvements in dry eye symptoms and signs such as tear film stability and volume.

CONFIDENTIALITY

Your responses to this informed consent will be anonymous. Please do not write any identifying information on your informed consent. Every effort will be made by the researcher to preserve your confidentiality including the following:

- Assigning code names/numbers for participants that will be used on all research notes and documents
- Keeping notes, interview transcriptions, and any other identifying participant information in a locked file cabinet in the personal possession of the researcher.

Participant data will be kept confidential except in cases where the researcher is legally obligated to report specific incidents. These incidents include, but may not be limited to, incidents of abuse and suicide risk.

CONTACT INFORMATION

If you have questions at any time about this study, or you experience adverse effects as the result of participating in this study, you may contact the researcher whose contact information is provided on the first page. If you have questions regarding your rights as a research participant, or if problems arise which you do not feel you can discuss with the Primary Investigator, Antonio Ballesteros Sánchez, please contact the Institutional Review Board at 617700530 EXT. +34.

VOLUNTARY PARTICIPATION

Your participation in this study is voluntary. It is up to you to decide whether or not to take part in this study. If you decide to take part in this study, you will be asked to sign a consent form. After you sign the consent form, you are still free to withdraw at any time and without giving a reason. Withdrawing from this study will not affect the relationship you have, if any, with the researcher. If you withdraw from the study before data collection is completed, your data will be returned to you or destroyed.

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CONSENT

I have read and I understand the provided information and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form. I voluntarily agree to take part in this study.

Participant's signature_____Date _____

Investigator's signature_____Date