TITLE

Comparative Effects of Autologous Serum, Umbilical Cord Blood-Derived Drops, and Platelet Lysate on Ocular Surface Parameters

Date: October 18 2023

Informed Consent Form

PART A

“Comparative study using eye drops derived from autologous peripheral blood, umbilical cord blood, and autologous serum in patients with ocular surface disease.”

1. INFORMATION

If you wish and agree to participate in the treatment using eye drops derived from autologous peripheral blood, umbilical cord blood, and autologous serum, the information provided in this document explains the purpose of this treatment, what will be required of you, and the benefits or possible risks of your participation. Any patient who wishes to undergo any treatment has the legal right to be informed about their condition and the recommended therapy by the treating physician, so that they can decide whether or not to proceed.

This information aims to inform the patient about the treatment and possible complications, not to discourage them, since it is certain that no therapeutic intervention is entirely free of adverse effects. The anticipated risks and unpleasant consequences of the treatment have been weighed against the individual benefit to the participant as well as to other patients, and for this reason the treatment is recommended by the treating physician.

Treatment begins only when the expected therapeutic and public health benefits outweigh the risks, and it continues only as long as compliance with this requirement is continuously monitored. The treating physician is responsible for informing the patient fully, objectively, clearly, and understandably about any potential complications during the application of the treatment.

2. TREATMENT

The proposed treatment with eye drops derived from autologous peripheral or umbilical cord blood or autologous serum is individualized and pertains exclusively to the patient. This agreement concerns solely the application of the biological material for therapeutic purposes.

The aim of the treatment is to improve the patient’s clinical condition in cases of direct administration, achieved through tissue regeneration. It is noted that all prerequisites are intended to guarantee both the safety of the product and the safety of the patient.

3. APPLICATION OF TREATMENT AND EFFECTIVENESS

The application of the treatment is always carried out in cooperation and agreement between the treating physician and the patient, who will jointly determine the date of administration. This date must be strictly observed by both parties, as the biological product has a limited lifespan; otherwise, there is a possibility of treatment failure.

The success of the treatment also depends on factors related to the patient's age, the size and location of the lesion, as well as the patient's behavior after the treatment. For this reason, the treating physician is responsible for providing instructions prior to any treatment regarding the protection of the cellular product and the patient's return to optimal functional status.

6. POSSIBLE COMPLICATIONS

The application of eye drops derived from autologous peripheral or umbilical cord blood or autologous serum carries absolutely no risk of infection, as they are fully tested before being sent to the treating physician.

7. CONFIDENTIALITY AND PRIVACY

All medical history and this consent form, which contain your personal information, will be kept confidential and with full respect for your personal data. To protect your personal information, all data containing personal and sensitive information will be stored in a secure location, with access permitted only to authorized personnel bound by confidentiality.

Additionally, all information and examination results will be stored in a secure file with access permitted only to authorized personnel bound by confidentiality.

If you agree to participate in the treatment, you give your consent, allow, and authorize the collection and use of your information in accordance with the terms of this document.

8. COST OF TREATMENT

The patient bears no financial burden for participation in the study.

9. AUTHORIZATION

By signing this document voluntarily and freely, and with full commitment from the responsible laboratory to maintain confidentiality and protect your personal data, you agree and consent to participate in the treatment using eye drops derived from autologous peripheral or umbilical cord blood or autologous serum.

You acknowledge, accept, and confirm that you have been previously informed and have received all written and oral information regarding the treatment, the possible risks and benefits, as well as alternative options.

You consent to the collection and use of your personal data. You fully understand that this data is necessary and will be used for the correct identification of the results.

10. PATIENT CONSENT

I, the undersigned, have carefully read and fully understood all the above information, both oral and written, as well as the information provided in this document. I have discussed the risks and benefits arising from treatment with eye drops derived from autologous peripheral or umbilical cord blood or autologous serum, and I have received satisfactory answers to all my questions.

I agree, consent, and accept the use of the autologous treatment and release my physician and the responsible laboratory preparing the eye drops from any liability in the event of treatment ineffectiveness or possible complications that may arise.

In the event that the material is not suitable for clinical use, I consent, without compensation, to its use in research or in the laboratory for quality control, without the use of my personal data or that of my child.

PATIENT NAME ……

SIGNATURE ……

PHYSICIAN NAME ……

SIGNATURE ……