Patient information[1] and informed consent to participate in the clinical trial

Therapy of Age-related Macular Degeneration Through Training With the Medical Eye Trainer

EK number: 1241/2021 KUK Linz

Dear participant!

The Medical Eye Trainer (MET) is based on a long-known and old training method for poor eyesight and it is the modern implementation of this therapy on an electronic device. The positive effect of this method was shown in a first, smaller study a few years ago. Since then, the method has been used successfully for age-related macular degeneration in a small environment.

No therapy changes or deviations from the MET therapy that is already in use will be made in the study. The data and values of the eyes are recorded and evaluated during your treatment. By participating in the study, there is no change in risk compared to the Medical Eye Trainer therapy that is already in use. Since this therapy has not yet found general widespread use, the study participants are protected by insurance.

Every therapy is associated with risks and side effects. These are not changed by the study. All possible undesirable effects are explained in detail below.

We invite you to take part in the above clinical study. The explanation about this takes place in a detailed medical discussion.

Your participation in this clinical study is voluntary. You can withdraw from the study at any time without giving a reason. The refusal to participate or an early withdrawal from this study will not have any negative consequences for your medical care.

Clinical studies are necessary in order to obtain reliable new medical research results. An indispensable requirement for the implementation of a clinical study, however, is that you declare your consent to participate in this clinical study in writing. Please read the following text carefully as a supplement to the informational discussion with your doctor and do not hesitate to ask questions.

[1] In order to improve readability, the simultaneous use of feminine and masculine personal terms is partly dispensed with in the rest of the text. Both genders are always meant and addressed - if applicable.

Please only sign the declaration of consent

- if you have fully understood the nature and course of the clinical study,
- when you are ready to agree to participate and
- if you are aware of your rights as a participant in this clinical trial.

The responsible ethics committee issued a favorable opinion on this clinical study as well as on patient information and the declaration of consent.

1. What is the purpose of the clinical study?

The Medical Eye Trainer is currently a therapy that is used and widely used in a small setting. The purpose of the study is to spread this new treatment across the board. The Medical Eye Trainer is therefore a method that may still be unknown and new to you. The purpose of the clinical study is to examine the rapid improvement in your poor eyesight in age-related macular degeneration (AMD). Data about the course of your therapy are collected and evaluated.

2. How does the clinical study work?

This clinical trial will be conducted at our clinic and a total of 150 people will take part.

Your participation in this clinical trial is expected to take 2 months with follow-up visits.

<u>The following measures are carried out:</u>

In addition to any other AMD therapy, the diseased eye is trained with a stimulation system for 90 seconds per day. This therapy is carried out with a commercially available tablet computer or smartphone that you own. The application must be carried out while sitting. For safety reasons, a supervisor is required for the first five uses. The supervisor is also not allowed to identify any of the contraindications listed below. Your eye findings will be recorded before and after the study. This examination is no different from your usual check-up. Data relevant to the study include: eyesight, retinal measurement using optical coherence tomography (OCT), medical history and eye findings using a slit lamp.

3. What are the benefits of participating in the clinical trial?

It is possible that participation in the study will improve the vision of the diseased eye more quickly.

4. Are there any risks, complaints and side effects?

These risks and side effects also exist with therapy using the MET system and will not be changed by the study.

The following side effects can occur as a result of the application of the therapy:

Double vision, dizziness, nausea, irritation of the surface of the eye, epilepsy.

In this case you can contact the attending physician at any time.

If these symptoms exist before the therapy, you cannot participate. If relatives are known to have epilepsy, participation is also not possible.

5. Additional medication?

No additional drugs are required for these examinations.

6. Does participation in the clinical trial have any other lifestyle effects and what are the obligations?

Participation in this study does not require any lifestyle changes.

7. What to do if symptoms, accompanying symptoms and / or injuries occur?

Should one of the symptoms listed above or other accompanying symptoms occur in the course of the clinical study, you must inform your doctor of these, in the event of serious accompanying symptoms immediately, if necessary by telephone (see telephone numbers below).

8. Insurance

As a participant in this clinical trial, you have the legally required no-fault insurance coveragez (Personal injury insurance in accordance with Section 47 of the Medical Devices Act, which covers all damagecovers that may be caused in your life or health by the measures of the clinical investigation carried out on you, with the exception of damage due to changes in the genetic material in cells of the germline.

The insurance was taken out for you with Zurich Insurance under the policy number OF-25692483-8. If you wish, you can inspect the insurance documents.

In the event of a claim, you can contact the insurer directly and make your own claims. Austrian law applies to the insurance contract; insurance claims are enforceable in Austria.

You can also contact the patient advocate, patient representative or patient ombudsman for support.

In order not to endanger the insurance cover

- You may only undergo other medical treatment during the duration of the clinical trial with the consent of your treating investigator (with the exception of emergencies). This also applies to taking additional medication or participating in another study.

- you must immediately notify the treating investigator - or the above-mentioned insurance company - of any damage to health that could have occurred as a result of the clinical trial.
- you must do everything reasonable to clarify the cause, course and consequences of the insured event and to keep the damage to a minimum. This may also include authorizing your treating physicians to provide the information required by the insurer.

9. Information for women of childbearing potential

As a woman of childbearing potential, you can take part in the clinical trial.

If you become pregnant during the clinical trial or if you suspect that you may have become pregnant, please inform your investigator immediately.

10. When will the clinical trial be terminated early?

You can withdraw your willingness to participate and withdraw from the clinical study at any time without giving reasons, without incurring any disadvantages for your further medical care.

Your study doctor will immediately inform you of any new information that becomes known in relation to this clinical study and that could become material to you. On this basis, you can then reconsider your decision to continue participating in this clinical study.

However, it is also possible that your study doctor may decide to terminate your participation in the clinical trial prematurely without first obtaining your consent. The reasons for this can be:

a) They cannot meet the requirements of the clinical study;

b) Your study doctor has the impression that further participation in the clinical study is not in your interest.

11th How will the data collected from this clinical study be used?

As part of this clinical trial, data about you will be collected and processed. There is a fundamental distinction between

- those personal data by means of which a person can be directly identified (e.g. name, date of birth, address, social security number, pictures ...),
- Pseudonymized personal data, i.e. data in which all information that allows direct conclusions to be drawn about the specific person is either removed, replaced by a code (e.g. a number) or (e.g. in the case of pictures) made illegible. However, despite compliance with these measures, it cannot be completely ruled out that inadmissible re-identification occurs.

- anonymized data, which cannot be traced back to the specific person.

The investigator and other employees of the trial center who are involved in the clinical trial or your medical care have access to the data by which you can be directly identified (see point 1). In addition, authorized agents who are bound to secrecy can use theLead Ethics Commission Upper Austria sowThe representatives of domestic and / or foreign health authorities and the respective responsible ethics committees can inspect this data, insofar as this is necessary to check that the clinical trial is being carried out properly. All persons who have access to this data are subject to the respective applicable national data protection regulations and / or the EU General Data Protection Regulation (GDPR) when handling the data.

The code that enables the pseudonymised data to be assigned to you is only stored at your test center.

The data is only passed on in pseudonymized or anonymized form.

Only the pseudonymized or anonymized data will be used for any publications.

In the context of this clinical trial, there is no provision for data to be passed on to countries outside the EU (third country).

Your consent forms the legal basis for the processing of your personal data. You can revoke your consent to the collection and processing of your data at any time without giving a reason. After your revocation, no further data will be collected about you. The data collected up to the point of revocation can, however, continue to be processed in the context of this clinical trial.

According to the GDPR, you have the right to information, correction, deletion, restriction of processing, data portability and objection, as long as this does not make the aims of the clinical trial impossible or seriously impaired and unless other statutory provisions contradict this.

You do not have the right to delete your data processed in the context of this clinical trial, as provided for in the GDPR, due to the provisions of the Medicines Act and Medical Devices Act. In addition, the right to data portability is invalidated in the case of a clinical trial under the Medicines Act.

The expected duration of the clinical trial is two months. The duration of the storage of your data beyond the end or termination of the clinical trial is regulated by legal provisions.

If you have any questions about the handling of your data in this clinical trial, please contact your investigator first. If necessary, they can forward your request to the persons responsible for data protection.

Contact details of the data protection officers of the institutions involved in this clinical trial:

Data protection officergte: Mag. Siegfried Gruber (OPP - Compliance GmbH), Mag. Pumberger Hospital Ried

You have the right to lodge a complaint with the Austrian data protection authority about the handling of your data (www.dsb.gv.at; E-mail:dsb@dsb.gv.at).

12. Are there any costs for the participants? Is there a reimbursement or compensation?

You will not incur any additional costs by participating in this clinical study. The MET software is provided free of charge for the study. A reimbursement of costs is not provided.

13. Opportunity to discuss further questions

Your study doctor and his staff will be happy to answer any further questions you may have in connection with this clinical study. We will also be happy to answer questions relating to your rights as a patient and participant in this clinical study.

Name of contact person: Prim. PD. Dr. Robert Hörantner

Always available at: +43 (0) 664 884 717 01

14. Should other treating physicians be informed of participation in the clinical trial?

It is not necessary to inform your general practitioner or established ophthalmologist that you are participating in this study.

15. Device usage

If you are provided with an end device to carry out the study, please note the following requirements:

a) Only use the device and the associated power supply unit if they are undamaged.
b) Only use the original power supply for charging.
c) Charge the device under supervision in a fire-safe place.
d) Only use the device during therapy in battery mode.
e) When using the device, keep a safe distance from water and other dangerous liquids.
f) Observe the operating instructions enclosed with the device and follow the instructions given there.

16. Declaration of Consent

Name of the patient:

Date of birth:

I agree to take part in the AMD and Therapies Clinical Trial. I have been informed that I can refuse participation without any negative consequences, in particular for my medical care.

I am from Ms / Mr (Dr.med.) .... in detail and understandable about the clinical trial, possible burdens and risks, as well I have been informed about the nature, significance and scope of the clinical trial, the existing insurance and the requirements that arise for me from it. I also have the text of this patient information and informed consent form in total eightPages includes, read. The investigator answered questions that came up in an understandable and satisfactory manner. I had enough time to make up my mind. I have no further questions at the moment.

I will obey the medical orders required to carry out the clinical trial, but I reserve the right to terminate my voluntary participation at any time without incurring any disadvantages, in particular for my medical care.

I expressly agree that my data collected as part of this clinical trial will be processed as described in the "Data Protection" section of this document.

In the event that I withdraw from the clinical trial, I agree that my samples will continue to be stored and analyzed as described in this information and - if applicable - in the information on the sub-studies:

O YES

O NO

I have received a copy of this patient information and declaration of consent. The original remains with the investigator.

....
(Date and signature of the patient)

....
(Date, name and signature of the responsible investigator)

(The patient receives a signed copy of the patient information and declaration of consent; the original remains in the investigator's study folder.)