MTS1 : Myopia Treatment Study 1
Month 30 Visit
30-month Follow-up Form

Patient ID: M01-004-2299

SECTION: VISIT INFORMATION **(VisitInformation_b_03)**

VISIT INFORMATION

1a. Investigator taking responsibility for the visit: AEP1 - Alexander E. Pogrebniak, M.D.

1b. Coordinator taking responsibility for the visit: 21 - Shelly T. Mares

2. Visit date: 08 Oct 2020 ☐ Missed

If *Missed*, reason:

If *Other*, describe:

OUT OF TARGET WINDOW

☑ **Visit was completed out of target window**

1. Reason visit was completed out of target window: Clinic appointment not available

1a. If *Other*, describe:

SECTION: MEDICAL HISTORY SINCE PREVIOUS VISIT **(MTS1MedHxFU_a_03)**

MEDICAL HISTORY SINCE PREVIOUS STUDY VISIT

1. Have there been any adverse ocular events since the last visit? (e.g., lid/conjunctival irritation, light sensitivity, near blur, and/or reading difficulty) No
If *Yes*, complete an Adverse Event report

Visual Acuity Testing: If there has been any report since the last office visit of an ocular-related adverse event that lasted more than 1 hour, then distance visual acuity should be measured using the E-ETDRS testing protocol without cycloplegia. Note that adverse events such as transient burning, stinging, blur, or eye irritation that occur upon installation of the eyedrop that last LESS THAN ONE HOUR would NOT require visual acuity testing at the next office visit.

2. Have there been any adverse systemic events within 1 hour of study medication since the last visit? (e.g., dry skin/mouth, tachycardia, fever, flushing, irritability, mental confusion, constipation, aggravation of asthma, or seizures) No
If *Yes*, complete an Adverse Event report

3. Have there been any serious adverse events since the last visit? No
If *Yes*, complete an Adverse Event report

A serious adverse event is any untoward occurrence that:

- Results in death.
- Is life-threatening; (a non-life-threatening event which, had it been more severe, might have become life-threatening, is not necessarily considered a serious adverse event).
- Requires inpatient hospitalization or prolongation of existing hospitalization.
- Results in persistent or significant disability/incapacity or substantial disruption of the ability to conduct normal life functions (e.g., sight-threatening).
- Is considered a significant medical event by the investigator based on medical judgment (e.g., may jeopardize the participant or may require medical/surgical intervention to prevent one of the outcomes listed above).

4. Is the participant undergoing any treatment for myopia besides study drops? No

4a. If *Yes*, specify:

5. Menarche status: Male

If post-menarche, complete the following:

5a. Pregnancy test:
"If pregnancy test result is positive, study treatment should be discontinued (record in the treatment prescribed section)."

5b. PEDIG ID of person interpreting test results:

SECTION: COMPLIANCE ASSESSMENT (MTS1CompAssess_a_01)

COMPLIANCE ASSESSMENT

1. Were remaining ampules of study medication brought to the visit? No

1a. Number of remaining ampules of study medication:

2. Was the participant's compliance calendar brought to the visit? Yes

2a. Assessment of compliance with study medication based on review of calendar and interview with parent and/or child:
N/A (30-month Visit)

3. Assessment of spectacle (or contact lens) wear compliance since last visit (after interview with parent and/or child):
Excellent (76% to 100% of waking hours)

SECTION: CLINICAL MEASURES (MTS1ClinicMeas_c_01)

DISTANCE VISUAL ACUITY TESTING

E-ETDRS Visual Acuity Testing

Testing must be performed in in each eye in habitual refractive correction, without cycloplegia, and using the E-ETDRS visual acuity protocol.

Distance visual acuity is required only at the 30-month follow-up visit; or any time an ocular adverse event is reported.

Not Done (Required)

If *Not Done (Required)*, give reason: ateteas

If done, complete the following:

1. Name of Certified Visual Acuity Tester:

2. Right Eye score:

3. Left Eye score:

BINOCULAR ACCOMMODATIVE AMPLITUDE

Testing must be done without cycloplegia and in habitual correction.

Accommodative amplitudes are measured with a study-specified accommodative near-point rule and the participant in their current spectacle or contact lens correction. The participant views a single column of 20/30 optotype letters attached to the near-point rule and is instructed to keep the letters in focus as the target is moved toward the participant and report when the letters blur. The near point of accommodation is recorded as the distance from the card to the participant's brow as measured on the rule in centimeters (round to the nearest half centimeter).

☐ **Not Done**

If *Not Done*, give reason:

If done, complete the following:

1. Near point of accommodation: 11.0 **cm**

SECTION: CLINICAL TESTING (MTS1ClinicTesting_b_02)

CYCLOPLEGIC AUTOREFRACTION

Cycloplegic autorefraction measurements must be made with cycloplegia.

Three summary measures in each eye of autorefraction with cycloplegia will be obtained using an autorefractor according to the procedures for cycloplegic autorefraction defined in the MTS1 Procedures Manual.

☐ **Not Done (enter reason below)**

Name of Certified Tester: 21 - Shelly T. Mares

Instrument Identifier: A0001

1. Cycloplegic autorefraction (measures meeting manufacturer's reliability criteria):

Reading #1 OD: [sph: -0.50] [cyl: +0.75] @ [axis: 92] **OS:** [sph: -0.75] [cyl: +0.75] @ [axis: 92]

Reading #2 OD: [sph:] [cyl:] @ [axis:] **OS:** [sph:] [cyl:] @ [axis:]

Reading #3 OD: [sph:] [cyl:] @ [axis:] **OS:** [sph:] [cyl:] @ [axis:]

If any readings not done, describe why not: d

AXIAL LENGTH MEASUREMENT and ADDITIONAL BIOMETRY

Axial length measurements and additional biometry must be made with cycloplegia according to the procedures in the MTS1 procedures manual.

Testing: Not Done

Enter the results of all measurements to the nearest hundredth millimeter (0.01 mm).
(measures meeting reliability criteria)

Name of Certified Tester (if different than above):

Instrument Identifier:

Reading 1:

Axial Length OD: mm	**OS: mm**		
Flat corneal radius OD: D	**OS: D**		
Anterior chamber depth OD: mm	**OS: mm**		
Lens thickness, if available OD: mm	**OS: mm**	☐ **Not Available**	

If any readings not done, describe why not: d

MASKED TESTING

1. Was ANY masked examiner able to identify the participant's treatment group at any time? No

If YES, detail in COMMENTS.

COMMENTS

SECTION: ASSIGN GIFT CARD (GiftCard_a_01)

GIFT CARD INFORMATION

1. Will user be assigned a Gift Card for this visit? No

i. If No, enter reason: test

SECTION: TREATMENT PRESCRIBED / COMPLETE THE VISIT (MTS1TreatRx_a_02)

TREATMENT PRESCRIBED

Spectacle or contact lenses correction must be updated whenever the investigator's standard refraction technique (with or without cycloplegia; over-refraction or without refractive correction) reveals a change in refractive error as follows:

- A difference of >0.75 D sphere
- A difference of >0.75D cylinder
- A difference of >0.50D in SE anisometropia
- A difference in axis of 6 degrees or more when the cylinder is ≥1.00D.

If updated, the refractive correction must meet the following requirements:

- Myopia (by spherical equivalent) in both eyes must be corrected to within ±0.50 D
- Cylinder power in both eyes must be within ±0.50 D
- Cylinder axis for both eyes must be within ±5 degrees of the axis when cylinder power is ≥ 1.00 D or within ±15 degrees when the cylinder power is <1.00 D.

1. Check <u>one</u> of the following: Continuing in current optical correction (no change required).

2. Do spectacles (and/or contact lenses) meet study criteria based on a standard refraction (with or without cycloplegia? Yes

3. Is study medication being continued at the protocol-specified dose? Yes

3a. If *<u>No</u>*, what is changing and why?
NOTE: If female participants have become pregnant, study medication must be discontinued.

4. Is any treatment for myopia besides study drops being prescribed? No

4a. If *<u>Yes</u>*, what is being prescribed and why?
NOTE: No treatment to slow myopia progression is allowed after 24 months. Correction of refractive error with spectacles or soft contact lenses is

allowed.

5. Site Location: 004A - Anchorage, AK

24-MONTH VISIT ONLY:

- Instruct family to discontinue study eye drops.
- No myopia treatment other than optical correction should be prescribed prior to the 30-month follow-up visit.

COMMENTS