

MTS1 : Myopia Treatment Study 1
Month 6 Visit
6-month Follow-up Form

Patient ID: **M01-004-2299**

SECTION: VISIT INFORMATION

(VisitInformation_b_03)

VISIT INFORMATION

1a. Investigator taking responsibility for the visit: tblMTS1VisitInfo.dbo.InvID
AEPI - Alexander E. Pogrebnik, M.D.

1b. Coordinator taking responsibility for the visit: tblMTS1VisitInfo.dbo.SiteCoordID
AEPI - Alexander E. Pogrebnik, M.D.

BM1: tblMTS1VisitInfo.dbo.ColumnName_Property_Not_Set_In_Template

2. Visit date: tblMTS1VisitInfo.dbo.VisitDt tblMTS1VisitInfo.dbo.VisitMiss
19 Jan 2018 ☐ Missed

If Missed, reason: tblMTS1VisitInfo.dbo.VisitMissReason

If Other, describe: tblMTS1VisitInfo.dbo.VisitMissReasonDs

OUT OF TARGET WINDOW

tblMTS1VisitInfo.dbo.OutOfWin **Visit was completed out of target window**
☒

1. Reason visit was completed out of target window: tblMTS1VisitInfo.dbo.OutOfWinReason
Bad weather

1a. If Other, describe: tblMTS1VisitInfo.dbo.OutOfWinReasonDs

SECTION: MEDICAL HISTORY SINCE PREVIOUS VISIT

(MTS1MedHxFU_a_01)

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)

tblMTS1MedHxFU.dbo.AESinceLast

No

If Yes, complete an Adverse Event report

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
tblMTS1MedHxFU.dbo.AE1Hr

If Yes, complete an Adverse Event report

3. Have there been any serious adverse events since the last visit? tblMTS1MedHxFU.dbo.SeriousAE

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? tblMTS1MedHxFU.dbo.MyopiaTx

No

4a. If Yes, specify: tblMTS1MedHxFU.dbo.MyopiaTxDs

COMPLIANCE ASSESSMENT

1. Were remaining ampules of study medication brought to the visit? tblMTS1CompAssess.dbo.AmpulesReturned

Yes

1a. Number of remaining ampules of study medication: tblMTS1CompAssess.dbo.AmpulesRemain

1

2. Was the participant's compliance calendar brought to the visit? tblMTS1CompAssess.dbo.CalendarReturned

Yes

2a. Assessment of compliance with study medication based on review of calendar and interview with parent and/or child:

tblMTS1CompAssess.dbo.MTS1MedCompl

Excellent (76% to 100%)

3. Assessment of spectacle (or contact lens) wear compliance since last visit (after interview with parent and/or child):

tblMTS1CompAssess.dbo.MTS1SpecCompl

Excellent (76% to 100% of waking hours)

SECTION: EYE DROP QUESTIONNAIRE

EYE DROP QUESTIONNAIRE

Questions are completed by the child about their experience with eye drops since the previous visit. If the child is unable to answer the questions, or if the question does not apply, select never.

THESE QUESTIONS ASK IF CERTAIN THINGS ARE HARD FOR THE CHILD

1. Do you hate eye drops? tblMTS1EyeDropQuest.dbo.HateEyedrops

Never

2. Do your eye drops hurt your eyes? tblMTS1EyeDropQuest.dbo.DropsHurtEyes

Never

3. Do you have a hard time seeing? tblMTS1EyeDropQuest.dbo.HardTimeSeeing

Never

4. Do you have trouble reading up close? tblMTS1EyeDropQuest.dbo.TroubleReading

Never

5. Does bright light make it hard to do things outside? tblMTS1EyeDropQuest.dbo.BrightLightOutside

Never

THESE QUESTIONS ASK IF THE CHILD IS BOTHERED BY CERTAIN THINGS

6. Are you bothered by how your eye drops make your eyes look? tblMTS1EyeDropQuest.dbo.BotherByLook

Never

7. Does it bother you because your eye drops hurt your eyes? tblMTS1EyeDropQuest.dbo.BotherHurt

Never

8. Does it bother you because you have a hard time seeing? tblMTS1EyeDropQuest.dbo.BotherHardSee

Never

9. Does it bother you because you have trouble reading up close? tblMTS1EyeDropQuest.dbo.BotherTroubleRead

Never

10. Does it bother you because bright light makes it hard to do things outside? tblMTS1EyeDropQuest.dbo.BotherLightOutside

Never

SECTION: CLINICAL MEASURES

DISTANCE VISUAL ACUITY TESTING

E-ETDRS Visual Acuity Testing

Testing must be performed 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.

tblMTS1ClinicMeas.dbo.DistVANotDoneReas

If **Not Done (Required)**, give reason: tblMTS1ClinicMeas.dbo.DistVANotDoneReasDs

If done, complete the following:

1. Name of Certified Visual Acuity Tester: tblMTS1ClinicMeas.dbo.DistVATestID
21 - Shelly T. Mares

2. Right Eye score: tblMTS1ClinicMeas.dbo.ETDRSVisAcuOD
76

3. Left Eye score: tblMTS1ClinicMeas.dbo.ETDRSVisAcuOS
77

NEAR VISUAL ACUITY TESTING

Binocular Near Visual Acuity testing is required only at the 6-month follow-up visit.

tblMTS1ClinicMeas.dbo.BinNrVANotDone **Not Done**

☐

If **Not Done**, give reason: tblMTS1ClinicMeas.dbo.BinNrVANotDoneDs

If done, complete the following:

Using the ATS4 Near Visual Acuity Test, measure near binocular visual acuity WITHOUT cycloplegia

1. Binocular Near VA: OU 20/ tblMTS1ClinicMeas.dbo.BinNrVAOU
20/12

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).

tblMTS1ClinicMeas.dbo.BinAccAmpNotDone **Not Done**

☐

If **Not Done**, give reason: tblMTS1ClinicMeas.dbo.BinAccAmpNotDoneDs

If done, complete the following:

1. Near point of accommodation: tblMTS1ClinicMeas.dbo.NrPtAcc cm
12.0

SECTION: CLINICAL TESTING

(MTS1ClinicTesting_b_01)

CYCLOPLEGIC AUTOREFRACTION

BM1: tblMTS1ClinicTesting.dbo.ColumnName_Property_Not_Set_In_Template

Readings should be taken 30 minutes \pm 5 minutes after the second drop of 1.0% cyclopentolate (one drop twice to each eye with 5 minutes between drops). If eyes are not sufficiently dilated and/or if the dilation has worn off before all cycloplegic procedures have been performed, another drop of 1% cyclopentolate may be administered, followed by an additional 30-minute wait before testing.

For each eye, three autorefraction measurements will be taken. For each measurement, the autorefractor will yield a final reading (either an individual reading or the mean/median of several individual readings, depending on the autorefractor) consisting of sphere, cylinder, and axis.

Enter readings from the printout generated by the autorefractor. Keep paper printouts in PEDIG paper forms binder.

tblMTS1ClinicTesting.dbo.AutoRefNotDone **Not Done (enter reason below)**

☐

BM2: tblMTS1ClinicTesting.dbo.ColumnName_Property_Not_Set_In_Template

Name of Certified Tester: tblMTS1ClinicTesting.dbo.AutoRefTesterID
21 - Shelly T. Mares

Instrument Identifier: tblMTS1ClinicTesting.dbo.AutoRefInstrID

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

Reading #1 OD: OS:

tblMTS1ClinicTesting.dbo.AutoRef1SphOD [sph: -1.00] [cyl: tblMTS1ClinicTesting.dbo.AutoRef1CylOD] @ [axis: tblMTS1ClinicTesting.dbo.AutoRef1AxisOD]	tblMTS1ClinicTesting.dbo.AutoRef1SphOS [sph: -1.50] [cyl: tblMTS1ClinicTesting.dbo.AutoRef1CylOS] @ [axis: tblMTS1ClinicTesting.dbo.AutoRef1AxisOS]
Reading #2 OD: tblMTS1ClinicTesting.dbo.AutoRef2SphOD [sph: -1.00] [cyl: tblMTS1ClinicTesting.dbo.AutoRef2CylOD] @ [axis: tblMTS1ClinicTesting.dbo.AutoRef2AxisOD]	OS: tblMTS1ClinicTesting.dbo.AutoRef2SphOS [sph: -1.50] [cyl: tblMTS1ClinicTesting.dbo.AutoRef2CylOS] @ [axis: tblMTS1ClinicTesting.dbo.AutoRef2AxisOS]
Reading #3 OD: tblMTS1ClinicTesting.dbo.AutoRef3SphOD [sph: -1.00] [cyl: tblMTS1ClinicTesting.dbo.AutoRef3CylOD] @ [axis: tblMTS1ClinicTesting.dbo.AutoRef3AxisOD]	OS: tblMTS1ClinicTesting.dbo.AutoRef3SphOS [sph: -1.50] [cyl: tblMTS1ClinicTesting.dbo.AutoRef3CylOS] @ [axis: tblMTS1ClinicTesting.dbo.AutoRef3AxisOS]

If any readings not done, describe why not: tblMTS1ClinicTesting.dbo.AutoRefNotDoneDs

BM3: tblMTS1ClinicTesting.dbo.ColumnName_Property_Not_Set_In_Template

AXIAL LENGTH MEASUREMENT and ADDITIONAL BIOMETRY

BM4: tblMTS1ClinicTesting.dbo.ColumnName_Property_Not_Set_In_Template Axial length and additional biometry measurements must be made with cycloplegia

tblMTS1ClinicTesting.dbo.AxialLenNotDone **Not Done (enter reason below)**
☐

BM5: tblMTS1ClinicTesting.dbo.ColumnName_Property_Not_Set_In_Template 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): tblMTS1ClinicTesting.dbo.AxialLenTesterID
21 - Shelly T. Mares

Instrument Identifier: tblMTS1ClinicTesting.dbo.AxialLenInstrID

Reading 1:

Axial Length OD: tblMTS1ClinicTesting.dbo.AxialLen1OD mm 15.00	OS: tblMTS1ClinicTesting.dbo.AxialLen1OS mm 15.00
Mean corneal radius OD: tblMTS1ClinicTesting.dbo.MeanCorneaRad1OD mm 7.00	OS: tblMTS1ClinicTesting.dbo.MeanCorneaRad1OS mm 7.00
Anterior chamber depth OD: tblMTS1ClinicTesting.dbo.AntChamDepth1OD mm 3.00	OS: tblMTS1ClinicTesting.dbo.AntChamDepth1OS mm 3.00
Lens thickness, if available OD: tblMTS1ClinicTesting.dbo.LensThick1OD mm 3.00	OS: tblMTS1ClinicTesting.dbo.LensThick1OS <input type="checkbox"/> Available 3.00 mm

Reading 2:

Axial Length OD: tblMTS1ClinicTesting.dbo.AxialLen2OD mm 15.00	OS: tblMTS1ClinicTesting.dbo.AxialLen2OS mm 15.00
Mean corneal radius OD: tblMTS1ClinicTesting.dbo.MeanCorneaRad2OD mm 7.00	OS: tblMTS1ClinicTesting.dbo.MeanCorneaRad2OS mm 7.00
Anterior chamber depth OD: tblMTS1ClinicTesting.dbo.AntChamDepth2OD mm 3.00	OS: tblMTS1ClinicTesting.dbo.AntChamDepth2OS mm 3.00

		mm	
Lens thickness, if available OD:	OS:		
tblMTS1ClinicTesting.dbo.LensThick2OD mm	tblMTS1ClinicTesting.dbo.LensThick2OS mm	tblMTS1ClinicTesting.dbo.LensThick2NA Not	
3.00	3.00	<input type="checkbox"/>	Available
Reading 3:			
Axial Length OD:	OS:		
tblMTS1ClinicTesting.dbo.AxialLen3OD mm	tblMTS1ClinicTesting.dbo.AxialLen3OS mm		
15.00	15.00		
Mean corneal radius OD:	OS:		
tblMTS1ClinicTesting.dbo.MeanCorneaRad3OD mm	tblMTS1ClinicTesting.dbo.MeanCorneaRad3OS mm		
7.00	7.00		
Anterior chamber depth OD:	OS:		
tblMTS1ClinicTesting.dbo.AntChamDepth3OD mm	tblMTS1ClinicTesting.dbo.AntChamDepth3OS mm		
3.00	3.00		
Lens thickness, if available OD:	OS:		
tblMTS1ClinicTesting.dbo.LensThick3OD mm	tblMTS1ClinicTesting.dbo.LensThick3OS mm	tblMTS1ClinicTesting.dbo.LensThick3NA Not	
3.00	3.00	<input type="checkbox"/>	Available
If any readings not done, describe why not: tblMTS1ClinicTesting.dbo.AxialLenNotDoneDs			

MASKED TESTING

1. Was ANY masked examiner able to identify the participant's treatment group at any time? tblMTS1ClinicTesting.dbo.Unblind

No

If YES, detail in COMMENTS.

COMMENTS

tblMTS1ClinicTesting.dbo.FormCmts

SECTION: TREATMENT PRESCRIBED / COMPLETE THE VISIT

(MTS1TreatRx_a_01)

TREATMENT PRESCRIBED

Refractive correction prescribed must meet the following criteria relative to the cycloplegic refraction:

- Refractive correction in each eye (single vision eyeglasses or contact lenses with any necessary adjustment for contact lens rotation and vertex distance) is based on the investigator's standard refraction technique (with or without cycloplegia) must meet the following criteria:
 - Myopia (by spherical equivalent) in both eyes must be corrected to within ± 0.50 D of the investigator's cycloplegic measurement of refractive error.
 - Cylinder power in both eyes must be within ± 0.50 D of the investigator's standard refraction technique, which can be based on a cycloplegic or non-cycloplegic refraction.
 - Cylinder axis for both eyes must be within ± 5 degrees of the axis found on the investigator's refraction when cylinder power is ≥ 1.00 D or within ± 15 degrees when the cylinder power is < 1.00 D.

Measurement of refractive error for assessing the above criteria may be performed as an over-refraction or without refractive correction.

- Best-corrected distance visual acuity in current correction meeting the following criteria:
 - 20/32 or better in each eye (≥ 76 letters by E-ETDRS testing)
 - Interocular difference ≤ 0.1 logMAR (≤ 5 letters by E-ETDRS testing)

1. Check one of the following: tblMTS1TreatRx.dbo.MTS1CorrRx

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)?

tblMTS1TreatRx.dbo.SpecsMetCrit

Yes

3. Is study medication being continued at the protocol-specified dose? tblMTS1TreatRx.dbo.ContMed

Yes

3a. If No, what is changing and why? tblMTS1TreatRx.dbo.ContMedDs

NOTE: If female participants have become pregnant, study medication must be discontinued.

4. Is any treatment for myopia besides study drops being prescribed? tblMTS1TreatRx.dbo.MTSTreatRx

No

4a. If Yes, what is being prescribed and why? tblMTS1TreatRx.dbo.MTSTreatRxDs

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: tblMTS1TreatRx.dbo.SiteLocID

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

tblMTS1TreatRx.dbo.FormCmts