MTS1 : Myopia Treatment Study 1
Month 18 Visit
18-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
AEP1 - Alexander E. Pogrebniak, M.D.

1b. Coordinator taking responsibility for the visit: tblMTS1VisitInfo.dbo.SiteCoordID
AEP1 - Alexander E. Pogrebniak, M.D.

BM1: tblMTS1VisitInfo.dbo.ColumnName_Property_Not_Set_In_Template

2. Visit date: tblMTS1VisitInfo.dbo.VisitDt
06 Feb 2018

tblMTS1VisitInfo.dbo.VisitMiss
☐ 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
Financial issue

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

SECTION: COMPLIANCE ASSESSMENT (MTS1CompAssess_a_01)

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 (MTS1EyeDropQuest_a_01)

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
Sometimes

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 (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.

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
7

3. Left Eye score: tblMTS1ClinicMeas.dbo.ETDRSVisAcuOS
5

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**
2.0

SECTION: CLINICAL TESTING (MTS1ClinicTesting_b_01)

CYCLOPLEGIC AUTOREFRACTION

BM1: tblMTS1ClinicTesting.dbo.ColumnName_Property_Not_Set_In_Template

Readings should be taken 30 minutes ± 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:
tblMTS1ClinicTesting.dbo.AutoRef1SphOD
[sph: +0.25] [cyl: tblMTS1ClinicTesting.dbo.AutoRef1CylOD] @ [axis: tblMTS1ClinicTesting.dbo.AutoRef1AxisOD]

OS:
tblMTS1ClinicTesting.dbo.AutoRef1SphOS
[sph: +0.25] [cyl: tblMTS1ClinicTesting.dbo.AutoRef1CylOS] @ [axis: tblMTS1ClinicTesting.dbo.AutoRef1AxisOS]

Reading #2 OD:
tblMTS1ClinicTesting.dbo.AutoRef2SphOD
[sph: +0.25] [cyl: tblMTS1ClinicTesting.dbo.AutoRef2CylOD] @ [axis: tblMTS1ClinicTesting.dbo.AutoRef2AxisOD]

OS:
tblMTS1ClinicTesting.dbo.AutoRef2SphOS
[sph: +0.25] [cyl: tblMTS1ClinicTesting.dbo.AutoRef2CylOS] @ [axis: tblMTS1ClinicTesting.dbo.AutoRef2AxisOS]

Reading #3 OD:

OS:

tblMTS1ClinicTesting.dbo.AutoRef3SphOD [sph: +0.25] [cyl: tblMTS1ClinicTesting.dbo.AutoRef3CylOD] @ [axis: tblMTS1ClinicTesting.dbo.AutoRef3AxisOD]

tblMTS1ClinicTesting.dbo.AutoRef3SphOS [sph: +0.25] [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_TemplateAxial 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_TemplateEnter 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

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 7.00 **mm**

OS: tblMTS1ClinicTesting.dbo.MeanCorneaRad1OS **mm** 7.00

Anterior chamber depth OD: tblMTS1ClinicTesting.dbo.AntChamDepth1OD 3.00 **mm**

OS: tblMTS1ClinicTesting.dbo.AntChamDepth1OS **mm** 3.00

Lens thickness, if available OD: tblMTS1ClinicTesting.dbo.LensThick1OD **mm** 3.00

OS: tblMTS1ClinicTesting.dbo.LensThick1OS 3.00 **mm** tblMTS1ClinicTesting.dbo.LensThick1NA **Not Available**

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 7.00 **mm**

OS: tblMTS1ClinicTesting.dbo.MeanCorneaRad2OS **mm** 7.00

Anterior chamber depth OD: tblMTS1ClinicTesting.dbo.AntChamDepth2OD 3.00 **mm**

OS: tblMTS1ClinicTesting.dbo.AntChamDepth2OS **mm** 3.00

Lens thickness, if available OD: tblMTS1ClinicTesting.dbo.LensThick2OD **mm** 3.00

OS: tblMTS1ClinicTesting.dbo.LensThick2OS 3.00 **mm** tblMTS1ClinicTesting.dbo.LensThick2NA **Not Available**

Reading 3:

Axial Length OD: tblMTS1ClinicTesting.dbo.AxialLen3OD **mm** 15.00

OS: tblMTS1ClinicTesting.dbo.AxialLen3OS **mm** 15.00

Mean corneal radius OD: tblMTS1ClinicTesting.dbo.MeanCorneaRad3OD

OS: tblMTS1ClinicTesting.dbo.MeanCorneaRad3OS **mm**

7.00 mm | 7.00

Anterior chamber depth OD: tblMTS1ClinicTesting.dbo.AntChamDepth3OD 3.00 mm | **OS:** tblMTS1ClinicTesting.dbo.AntChamDepth3OS mm 3.00

Lens thickness, if available OD: tblMTS1ClinicTesting.dbo.LensThick3OD mm 3.00 | **OS:** tblMTS1ClinicTesting.dbo.LensThick3OS 3.00 mm | tblMTS1ClinicTesting.dbo.LensThick3NA **Not 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