MTS1 : Myopia Treatment Study 1
Run-in FU Randomization Visit
Randomization Form

Patient ID: M01-004-2299

SECTION: VISIT INFORMATION (VisitInformation_a_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
21 - Shelly T. Mares
BM1: tblMTS1VisitInfo.dbo.ColumnName_Property_Not_Set_In_Template

2. Visit date: tblMTS1VisitInfo.dbo.VisitDt
19 Jan 2018

SECTION: OPTICAL CORRECTION / COMPLIANCE ASSESSMENT (MTS1OptCorrHxCompAssess_a_01)

OPTICAL CORRECTION HISTORY

1. Does participant's current correction meet eligibility criteria? tblMTS1OptCorrHxCompAssess.dbo.CurrCorrMetCrit
Yes

Verify spectacles with lensometry.
If No, have the glasses re-made and have family return as soon as possible.

To be eligible for randomization, the participant must be wearing refractive correction in each eye (single vision eyeglasses or soft, daily wear single vision contact lenses with any necessary adjustment for contact lens rotation and vertex distance) that meets the following criteria based on the refraction performed at enrollment (or on today's refraction if the refraction is being repeated today):

- 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.

COMPLIANCE ASSESSMENT

The remaining ampules of artificial tears and the compliance calendar must be brought to this visit in order to be eligible for randomization. To be eligible for randomization, participants must have been at least 90% compliant based on both ampule usage and number of days drops were recorded as used on the calendar log.

1. Were the remaining ampules of study medication brought to the visit? tblMTS1OptCorrHxCompAssess.dbo.AmpulAtVisit
Yes

Must be yes to be eligible for randomization; if No, participant ends study participation.

1a. Remaining number of ampules: tblMTS1OptCorrHxCompAssess.dbo.AmpulRemain
1

2. Was the participant's compliance calendar brought to the visit? tblMTS1OptCorrHxCompAssess.dbo.CalAtVisit
Yes

Must be yes to be eligible for randomization; if No, participant ends study participation.

2a. Number of days drops used since enrollment based on calendar log: tblMTS1OptCorrHxCompAssess.dbo.DaysDropsUsed
30

3. Was the participant able to instill drops on their own or with the help of a parent? tblMTS1OptCorrHxCompAssess.dbo.AbleToInstill
Yes

Must be yes to be eligible for randomization; if No, participant ends study participation.

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
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 **(MTS1ClinicMeas_a_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.

Best-corrected distance visual acuity in current correction must meet the following criteria for eligibility for randomization:

- 20/32 or better in each eye (≥ 76 letters by E-ETDRS testing)
- Interocular difference ≤ 0.1 logMAR (≤ 5 letters by E-ETDRS testing)

Otherwise, participant ends study participation.

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
76

NEAR VISUAL ACUITY TESTING

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).

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_TemplateIf the randomization exam is more than 4 weeks (>28 days) after the enrollment visit, the cycloplegic autorefraction must be repeated and eligibility criteria will be based on the repeat measures.

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

BM2: tblMTS1ClinicTesting.dbo.ColumnName_Property_Not_Set_In_Template

If required:

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.

Take three autorefraction readings at distance. Enter readings from the printout generated by the autorefractor. Keep paper printouts in PEDIG paper forms binder.

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: -1.00] [cyl: tblMTS1ClinicTesting.dbo.AutoRef1CylOD] @ [axis: tblMTS1ClinicTesting.dbo.AutoRef1AxisOD]

OS:
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

For study eligibility, **refractive error** determined by cycloplegic autorefraction (mean of 3 measures) must meet ALL of the following:

- Amount of myopia: -1.00 to -6.00 D spherical equivalent in each eye
- Astigmatism ≤1.50 D in both eyes
- Anisometropia < 1.00 D in spherical equivalent

AXIAL LENGTH MEASUREMENT and ADDITIONAL BIOMETRY

BM4: tblMTS1ClinicTesting.dbo.ColumnName_Property_Not_Set_In_Template

If the enrollment exam is more than 4 weeks (>28 days) from the randomization visit, axial length and additional biometry measurements must be repeated.

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

BM5: tblMTS1ClinicTesting.dbo.ColumnName_Property_Not_Set_In_Template

If required:

Axial length and additional biometry measurements must be made three times in each eye, with cycloplegia.

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
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
7.00
mm

OS: tblMTS1ClinicTesting.dbo.MeanCorneaRad3OS **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
Not Applicable

If YES, detail in COMMENTS.

COMMENTS

tblMTS1ClinicTesting.dbo.FormCmts

SECTION: MISCELLANEOUS ELIGIBILITY / COMPLETE RANDOMIZATION **(MTS1ConfRand_a_01)**

CONFIRMATION OF ELIGIBILITY FOR RANDOMIZATION

Reminder: This visit is <u>research related</u> to be paid for by the study and not billed to insurance.

BM1: tblMTS1ConfRand.dbo.ColumnName_Property_Not_Set_In_Template

Verify the following: *must be checked for eligibility*

- ☑ Parent understands the protocol and is willing to accept randomization to daily atropine or placebo eye drops.
- ☑ Parent has home phone (or access to phone) and is willing to be contacted by Jaeb Center staff and/or Investigator's site staff
- ☑ Relocation outside of area of an active PEDIG site within next 32 months is not anticipated
- ☑ Testing completed within 7 days of this visit

Name of investigator who has verified the participant's eligibility: tblMTS1ConfRand.dbo.InvID
AEP1 - Alexander E. Pogrebniak, M.D.

Site Location: tblMTS1ConfRand.dbo.SiteLocID
004A - Anchorage, AK

Were an additional 30 ampules of Artificial Tears given to subject during Run-In? tblMTS1ConfRand.dbo.AddlArtTears
No

COMMENTS

tblMTS1ConfRand.dbo.FormCmts