MTS1 : Myopia Treatment Study 1
Enrollment Visit
Enrollment 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
01 Jan 2018

SECTION: DEMOGRAPHICS/MEDICAL AND OCULAR HISTORY (MTS1DemoMedOcuHx_a_01)

DEMOGRAPHICS/MEDICAL AND OPTICAL CORRECTION HISTORY

1. Gender: tblMTS1DemoMedOcuHx.dbo.Gender
Male

Ethnicity and race must be self-reported by the study participant. Read the following questions (and answer choices as applicable) aloud to the study participant exactly as written and record the responses below:

2. Do you consider yourself Hispanic/Latino or not Hispanic/Latino: tblMTS1DemoMedOcuHx.dbo.Ethnicity
Hispanic or Latino

Click to see "Personal Census Data" for definitions

3. Which of the following racial designations best describes you? tblMTS1DemoMedOcuHx.dbo.Race
White

Click to see "Personal Census Data" for definitions

If *more than one race*, please specify: tblMTS1DemoMedOcuHx.dbo.RaceDs

4. Eye Color: tblMTS1DemoMedOcuHx.dbo.EyeColor
Brown

5. Biological parents with myopia:

5a. Does the biological mother have myopia? tblMTS1DemoMedOcuHx.dbo.MotherMyop
Yes

5b. Does the biological father have myopia? tblMTS1DemoMedOcuHx.dbo.FatherMyop
Yes

Post-menarche female participants must have a negative in-office urine pregnancy test.

6. Menarche status: tblMTS1DemoMedOcuHx.dbo.MenarcheStatus

If *post-menarche*, complete the following:

6a. Pregnancy test: tblMTS1DemoMedOcuHx.dbo.PregnancyStatus

6b. PEDIG ID of person interpreting test results: tblMTS1DemoMedOcuHx.dbo.PregnancyInterpID

7. All of the following must be true for the participant to be eligible: BM1: tblMTS1DemoMedOcuHx.dbo.ColumnName_Property_Not_Set_In_Template

- ☑ Participant has no current or previous treatment with atropine, pirenzepine, or other anti-muscarinic agent
- ☑ Participant has no current or previous use of bifocals, progressive-addition lenses, or multi-focal contact lenses
- ☑ Participant has no current or previous use of Ortho-K, rigid gas permeable, or other contact lenses being used to reduce myopia progression
- ☑ Participant has no known atropine allergy
- ☑ Participant has no abnormality of the cornea, lens, central retina, iris, or ciliary body

Participant has no current or prior history of any of the following functional defects:

- ☑ Participant has no manifest strabismus
- ☑ Participant has no amblyopia
- ☑ Participant has no nystagmus
- ☑ Participant has no prior eyelid, strabismus, intraocular, or refractive surgery

☑ Participant has no diagnosis of Down syndrome or cerebral palsy
☑ Gestational age at least 32 weeks
☑ Birth weight more than 1500g
☑ Post-menarche female participants have a negative in-office urine pregnancy test
☑ Parent understands the protocol and is willing to accept randomization to daily atropine or placebo eye drops.
☑ Parent has a 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.
☑ Investigator has verified participant is willing to instill one drop in each eye each night, with or without parental assistance, after being provided with a demonstration on how to do so.

8. Does participant currently wear single-vision spectacles? tblMTS1DemoMedOcuHx.dbo.CurrSpecs
Yes

9. Does participant currently wear single-vision soft contact lenses (with or without spectacles)? tblMTS1DemoMedOcuHx.dbo.CurrContacts
Yes

10. Does current refractive correction meet protocol criteria: tblMTS1DemoMedOcuHx.dbo.RefCorrMeetCrit
Yes

If *No*, prescribe glasses that meet criteria.

Eligibility Criteria for Refractive Correction

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:

- *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.

SECTION: CLINICAL TESTING (MTS1ClinicTesting_a_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.

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: -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: **OS:**

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]

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

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).

BM5: tblMTS1ClinicTesting.dbo.ColumnName_Property_Not_Set_In_Template

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**

SECTION: MISCELLANEOUS ELIGIBILITY / COMPLETE ENROLLMENT (MTS1CompEnroll_a_01)

MISCELLANEOUS ELIGIBILITY / COMPLETE ENROLLMENT

1. Optical correction prescribed: tblMTS1CompEnroll.dbo.OptCorrRx

Continuing in current optical correction (no change required)

Changes in glasses are paid for by the study; changes to contact lenses are not paid for by the study

2. Do spectacles (and/or contact lenses) meet the following study criteria? tblMTS1CompEnroll.dbo.SpecCritMet

Yes

Refractive correction prescribed must meet the following criteria:

- *Refractive correction in each eye (single vision eyeglasses or contact lenses with any necessary adjustment for contact lens rotation and vertex distance) that meets 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.*

If the participant meets all eligibility criteria for the run-in phase (see section 2.2) but their current correction does not meet the requirements for randomization, then new refractive correction (or a change in refractive correction) can be prescribed in order to meet the requirements when the participant returns for potential randomization. A new (or change) in refractive correction can also be prescribed if the investigator elects to change a smaller amount of refractive error, but the resulting prescription must meet the criteria above. The prescribed correction can be single vision eyeglasses or contact lenses.

3. Verify all of the following *(all must be checked to be eligible):* BM1: tblMTS1CompEnroll.dbo.ColumnName_Property_Not_Set_In_Template

- ☑ Parent and child are willing to have artificial tears prescribed for 2 to 4 weeks.
- ☑ Child is able to place eye drops with or without parent's assistance.

ID number of investigator who has verified the participant's eligibility: tblMTS1CompEnroll.dbo.InvID

AEP1 - Alexander E. Pogrebniak, M.D.

tblMTS1CompEnroll.dbo.PtContactComp

☑ Participant Contact Information Form has been completed

*****Fax Form to the Jaeb Center within 24 hours (1-888-697-3344)*****

COMMENTS

tblMTS1CompEnroll.dbo.FormCmts