

A Randomized Trial to Evaluate Sequential vs Simultaneous Patching

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 3 years to 13 years old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

1. Age 3 to <13 years at the time of randomization
2. Amblyopia associated with anisometropia, strabismus, or both

o Criteria for strabismic amblyopia: At least one of the following must be met:

* Presence of a heterotropia on examination at distance or near fixation (with or without optical correction)

* Documented history of strabismus which is no longer present (which in the judgment of the investigator could have caused amblyopia)

* Criteria for anisometropia: At least one of the following criteria must be met:

- * 1.00 D difference between eyes in spherical equivalent (SE)
- * 1.50 D difference in astigmatism between corresponding meridians in the two eyes
- * Criteria for combined-mechanism amblyopia: Both of the following criteria must be met:

- Criteria for strabismus are met (see above)
 - o 1.00 D difference between eyes in spherical equivalent OR ≥ 1.50 D difference in astigmatism between corresponding meridians in the two eyes
 1. No previous treatment for amblyopia, including no more than 24 hours of spectacle wear.
 2. Investigator planning to initiate spectacle correction of refractive error meeting the following criteria based on a cycloplegic refraction that has been performed within 30 days:
 1. Full correction of anisometropia
 2. Full correction of astigmatism with the same axis found by the cycloplegic refraction
 3. Full correction of any myopia
 4. Hyperopia must not be under corrected by more than 1.50 D, and reduction in plus sphere must be symmetric in the two eyes.
 1. At enrollment, single VA measured in each eye assessed in trial frames with the spectacle correction the investigator plans to prescribe, using the investigator's routine method as follows:
 - VA in the amblyopic eye 20/40 to 20/200 inclusive.
 - Age-normal VA in the fellow eye: 40, 41
 - o 3 years: 0.4 logMAR (20/50) or better
 - o 4 years: 0.3 logMAR (20/40) or better
 - o 5-6 years: 0.2 logMAR (20/32) or better
 - o 7-12 years: 0.12 logMAR (78 letters) or better
- Interocular difference ≥ 3 logMAR lines (0.3 logMAR) or ≥ 15 letters
 - o When participants return for the Spectacle Baseline / Randomization Visit with their new spectacles, they will need to meet the same criteria as above using the ATS-HOTV or E-ETDRS protocol after wearing the new spectacles for at least 10 minutes (based upon the mean of a test and retest of VA in those new spectacles).
 - 1. Investigator is willing to prescribe spectacle wear followed sequentially by patching or simultaneous spectacles and patching treatment per protocol.
 - 2. Parent understands the protocol and is willing to accept randomization.
 - 3. Parent has phone (or access to phone) and is willing to be contacted by Jaeb Center staff or other study staff.
 - 4. Relocation outside of area of an active PEDIG site for this study within the next 56 weeks is not anticipated.

Exclusion Criteria:

1. Myopia greater than -6.00 D spherical equivalent in either eye.
2. Previous intraocular or refractive surgery.
3. Planned strabismus surgery in the next 56 weeks.
4. Any previous treatment for amblyopia (patching, atropine, Bangerter filter, vision therapy, or binocular treatment).
5. Previous spectacle or contact lens wear for more than 24 hours.
6. Parent and participant willing to forego option of contact lens wear for the duration of the study.
7. Ocular co-morbidity that may reduce VA determined by an ocular examination performed within the past 7 months (Note: nystagmus per se does not exclude the participant if the above VA criteria are met).
8. Severe developmental delay that would interfere with treatment or evaluation (in the opinion of the investigator). Participants with mild speech delay or reading and/or learning disabilities or attention deficit hyperactivity disorder (ADHD) are not excluded.
9. Known allergy to adhesive patches.
10. Known allergy to silicone.

Conditions & Interventions

Interventions:

OTHER: Patching, OTHER: Glasses

Conditions:

Amblyopia

Keywords:

patching, glasses, spectacles, simultaneous, sequential

More Information

Description:

A randomized trial to determine whether simultaneous treatment with spectacles and patching has an equivalent VA outcome compared with sequential treatment, first with spectacles alone followed by patching (if needed), for previously untreated amblyopia in children 3 to <13 years of age.

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Principal Investigator ID:

Phase: PHASE3

IRB Number:

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