Consent to Participate in a Research Project Entitled

Effectiveness of Orthokeratology on Myopia Control

DESCRIPTION

Orthokeratology, or Ortho-k, changes the shape of your cornea by wearing specially designed contact lenses while you sleep. Each night before you go to bed, you put specially designed molding contact lenses on and then remove them when you wake up in the morning. The goal of wearing these contact lenses is to correct your vision so that your vision is clear during the day, without having to wear glasses or other types of contact lenses.

There are several different types of Ortho-k contact lenses made from different companies. We only use Ortho-K contact lenses that have been approved by the FDA.

Children in this study will be randomly assigned to either the Ortho-k group or the control group. Children assigned to the control group will continue to wear glasses and/or soft contact lenses and will not be fit with specially designed Ortho-K contact lenses.

SUBJECTS

We are asking 40-60 children between the ages of 6-13 to be involved in this study. Twenty-five to thirty-five children will be fit with the specially designed orthokeratology contact lenses and fifteen to twenty-five children will continue to wear glasses and/or soft contact lenses (control group). Children who participate in this study will be randomly assigned to the orthokeratology group or the control group.

To be eligible, your child must have an increase of myopia or nearsightedness by more than -1.00D in one year. Your child must have a prescription between -1.00D and -6.00D in at least one eye with astigmatism less than 1.50D. Best corrected vision must be 20/25 or better.

Finally, subjects must be willing and able to present to clinic for all necessary follow-up care. Subjects will be excluded from the study if they are non-compliant with the treatment, have ever had refractive surgery, trauma, or if they are current gas permeable lens wearers.

PROCEDURE

The first examination will take about 1.5 hours. The following tests will be measured: visual acuity, subjective refraction and autorefraction (with cycloplegia), ocular health examination, and other examinations that will measure the length of the eye, the shape of the eye, the thickness of the cornea, and dilation. For some of these measurements, drops will be instilled into both eyes.

For those assigned to the Ortho-k group, you will have an appointment to receive your contact lenses as well as to learn how to insert and remove them from your eye and how to care for them. You will also have appointments at 1-day (15 min), 1-week (15 min), 1-month (15 min), 3-months (15 min), 6-months (45 min), 12-months (1.5 hrs), 18-months(45 min) and 24-months(1.5 hrs).

For the first year of the study, your time commitment will be approximately five and a half hours. For the second year of the study, your time commitment will be approximately three hours.

You will have dilation drops instilled at the initial visit, 12 month visit, and 24 month visit. The entire length of the study is 2 years.

Ortho-k contact lenses and solutions will be provided at no cost.

The children assigned to the control group (those wearing spectacles and soft contact lenses) will have an identical initial examination to above, as well as a 6-month, 12-month and 24-month examination. Children assigned to the control group will continue to wear glasses and/or soft contact lenses. No new glasses or soft contact lenses will be prescribed unless the prescription has changed.

BENEFITS

Researchers will learn more about myopic progression in a young population. Orthokeratology participants will have improved vision throughout the day without the need for glasses or contact lenses.

RISKS

While orthokeratology is considered to be a safe and effective procedure by the American Academy of Ophthalmology, potential risks include mild lens binding upon awakening, corneal staining, solution allergy, fluctuating vision, irritation, redness, and in rare cases corneal infection. To minimize risk, you will be well educated on proper lens wear and care and will be provided with the appropriate solutions at no cost. Some participants may experience burning and stinging with the use of the dilation drops. You will be seen for frequent follow-up care and will have the 24 hour emergency contact information for the urgent care service at the Illinois Eye Institute (312-225-6200).

CONFIDENTIALITY

Your name and information will not be given out without your permission. Data from this project may be used in presentations, but will not contain your name and it will be part of a group.

COST OF THE STUDY

There is no cost for you to participate in this project. Orthokeratology lenses and contact lens solution will be provided to you for no charge. Orthokeratology related eye exams will be provided at no charge. Subjects in the control group (spectacle and/or contact lenses) will receive updated glasses and/or contact lenses at no cost as needed (≥0.50 D change) throughout the study. If the subjects in the control group break their glasses, 50% cost of new spectacle will be covered. You will not be paid to participate in this study.

CONTACT PERSONS

If you have any questions about this study, please contact the lead researcher of this study, Dr. Jennifer Harthan at 312-949-7137. If you have questions about your rights as a research subject, please call the chair of the Institutional Review Board, Dr. Bob Donati at 312-949-7136.

PARTICIPATION IN THIS STUDY

You do not have to participate in this study. You can stop at any time. We can remove you at any time. If any of these happen it will not affect your eye care at the Illinois Eye Institute.

PHONE NUMBERS

Dr. Jennifer Harthan: 312-949-7137 Dr. Bob Donati: 312-949-7136

SIGNATURES

Study Participant Name

Print

_____Date _____

Signature

_____Date _____

Signature (Children ages 7 and older)

Witness Signature

_____Date_____