Title: Otoacoustic Emission Suppression Study

Number: NCT04749524

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Project Funded by NIH NIDCD SBIR Grant R44-DC018491-01A to Intelligent Hearing Systems Corp.

Grant Title:
Optimized Medial Olivocochlear Reflex Screening and Testing Module

Study Protocol and Statistical Analysis Plan

Study Protocol:

Objective:
The objective of this study is to develop an optimized hearing testing method using otoacoustic emissions (OAE), that can be used to efficiently assess peripheral neural function (including retrocochlear disorders) using the medial olivocochlear reflex (MOCR). This reflex has been shown to be abnormal in patients with neural disorders. The focus of this project will be the development of a screening method that incorporates OAE screening and measurement of the MOCR in the same test procedure. The target population in the proposed research is infants, particularly those in environments where auditory brainstem response (ABR) screening is not performed routinely. Addition of the MOCR to screening where ABR is not performed will address the shortcoming of OAE screening which misses neural forms of hearing loss.

Design:
The study uses an observational Case-Control design comparing the MOCR measures of individuals with normal hearing with those with hearing loss in a typical clinical recording environment. MOCR measurements were conducted in one session.

Methods:

The testing procedure is explained to the subjects, or their parents, and they are asked to sign an Informed Consent Form approved by the Vanderbilt University Medical Center Institutional Review Board.

A small rubber or foam tip is placed in the entrance of the ear canal during all tests. The tip is connected to earphones for behavioral hearing testing, or a middle ear muscle reflex or OAE measurement probe.

Adult and child subjects are first tested using behavioral hearing techniques to determine hearing thresholds and middle ear muscle reflexes. Behavioral hearing testing requires a subject to indicate if they hear sound tones being presented. The subject is asked to raise their hand or push a button when they hear tones delivered through earphones. Sound tones are varied in intensity and frequency to determine the subject's audiogram.

For the middle ear muscle reflex testing and OAE testing, the subject will be asked to sit quietly while sounds are played into their ears. Middle ear muscle reflexes use an ear probe to present a sound tone and measure changes in the sound pressure level of the tone caused by middle ear muscle contractions associated with the presentation of a loud ipsilateral (same ear) or contralateral (opposite ear) sound.

All subjects were tested with the OAE MOCR technique. During OAE MOCR testing, sounds are presented to the ear and a very sensitive microphone in a probe measures very tiny sounds generated by the ear in response to the sounds presented.

Measurements are conducted in one session lasting less than two hours. Adult and child subjects are given the option of watching a silent movie during the test. Infant subjects are typically tested during natural sleep.

Statistical Analysis Plan (SAP):

MOCR strength data was analyzed across defined spectral bands using a special version of the IHS Smart TrOAE module. Frequency domain data are obtained using fast Fourier transforms (FFT). Like conditions (i.e., without elicitor; with elicitor) were compared for data consistency within subjects to quantify variability. Following individual quantification, data will be compared across subjects. Subjects with noisy OAEs (physiological or ambient acoustical noise) will be excluded from the final analysis.

Planned statistical procedures for the above experiments included analysis of variance and t-tests to determine the effects of the testing factors on the dependent variables (MOCR strength, noise, sweeps and test time). A linear mixed effects model, grouping the data by each of the testing factors and levels, will be used to develop a regression model between the various factors and dependent variables. Distributions from the infant data will provide preliminary information to consider related to sensitivity and specificity. The proposed MOCR methods will be compared to TEOAE and ABR newborn screening information.

Informed Consent Form and IRB Approvals (2019-2022):

Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Linda J. Hood, Ph.D. Version Date: 7/1/2020

Study Title: Otoacoustic Emission Suppression in Clinical Populations
Institution/Hospital: Vanderbilt University

This informed consent document applies to adults

Name of participant: _____ Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Your participation in this research study is voluntary. You are also free to withdraw from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to participate in it, you will be notified so that you can make an informed decision whether or not to continue your participation in this study.

1. Purpose of the study:

We are doing this research so we can find out more about how babies, children and adults with speech and hearing problems hear and understand speech.

You are being asked to participate in this research study because you have a hearing or communication difficulty or have been asked to be part of a control group. Please know that whether or not you choose to participate will not in any way impact the clinical services you may be receiving.

2. Procedures to be followed and approximate duration of the study:

During the study, you will participate in a test session lasting approximately 1 to 2 hours. All test procedures are safe, non-invasive and are similar to those used regularly in audiology clinics. The tests will include:

- Behavioral hearing test
- Middle ear muscle reflex testing
- Otoacoustic Emissions (OAE) test

You will have rubber or foam plugs placed in the entrance of your ears during both tests. For the hearing test you will be asked to raise your hand or push a button when you hear tones delivered through the earphones. For the OAE testing, you will be asked to sit still and quiet while sounds are played into your ears. The goal of OAE testing is to measure a tiny sound that the ear generates when we play clicks and noise into the ears. You will be given the option of watching a silent movie during the test.

You may choose to withdraw from the study at any time.

3. Expected costs:

There are no expected costs to you for this study with the exception of travel to and from the Vanderbilt Bill Wilkerson Center.

4. Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

None of the test activities should be uncomfortable. Potential risks of participation include possible redness of the ear canal from the pressure of the earplug. Inconveniences include the time it takes to commute to the Vanderbilt Bill Wilkerson Center and to participate in the tests.

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5. Unforeseeable risks:

There are no unforeseeable risks associated with participation in this study.

6. Anticipated benefits from this study:

a) The potential benefits to science and humankind that may result from this study are that we might better understand the way in which individuals with hearing and speech problems process speech.
b) The potential benefit to you from participating in this study is a free hearing screening.

7. Compensation for participation:

Monetary compensation will be provided in the form of a check mailed to you following the completion of a testing session. Checks are generally mailed within 4-6 weeks after you complete a test session. You will be paid $15.00 per hour upon completion of a test session. Completion of the test session is where useable information is obtained. You will be paid $15.00 for an incomplete test session since you had to travel to the test. A session is "incomplete" if no useable data is obtained for reasons including, but not limited to, the test session being stopped by the research investigator(s) for reasons such as equipment failure.

8. Circumstances under which the Principal Investigator may withdraw you from study participation:

You may be withdrawn from the study if testing reveals that you present with greater than mild hearing loss, or if testing cannot be completed in 2 sessions. You will also be withdrawn if you indicate that you do not wish to participate.

9. What happens if you choose to withdraw from study participation:

There is no penalty for withdrawing from the study. Your participation is voluntary.

10. Contact Information. If you should have any questions about this research study or possibly injury, please feel free to call the Principal Investigator**, (Linda J. Hood, Ph.D.)** at **(615-936-4612)**.

For additional information about giving consent or your rights as a participant in this study, please feel free to contact the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

11. Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Information will be coded and stored in a locked file cabinet in a locked room of Dr. Hood's research laboratory. Only Dr. Hood and her approved research associates will have access to these files. Any information that is published will be in group form or completely without identifying information.

Principal Investigator: Linda J. Hood, Ph.D. Version Date: 7/1/2020

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STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

I agree to be contacted for future hearing studies for which I may be a good candidate.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Linda J. Hood, Ph.D. Version Date: 7/1/2020
Study Title: Otoacoustic Emission Suppression in Clinical Populations
Institution/Hospital: Vanderbilt University

This informed consent document applies to parents/guardians

Name of participant: _____ Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Your participation in this research study is voluntary. You are also free to withdraw from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to participate in it, you will be notified so that you can make an informed decision whether or not to continue your participation in this study.

1. Purpose of the study:

We are doing this research so we can find out more about how babies, children and adults with speech and hearing problems hear and understand speech.

Your child is being asked to participate in a research study because he/she has a hearing or communication difficulty or has been asked to be part of a control group. Please know that whether or not your child chooses to participate will not in any way impact the clinical services you may be receiving.

2. Procedures to be followed and approximate duration of the study:

If your child is an infant, all hearing testing will be performed in a single session while your baby is in the NICU or newborn nursery. Older children will be tested in our research laboratory at the Vanderbilt Bill Wilkerson Center on the 10th floor of Medical Center East, South Tower. Hearing tests will take approximately half an hour (infants) up to two hours (older babies and children). The hearing tests may include:

- Behavioral hearing test
- Middle ear reflex testing
- Otoacoustic Emissions (OAE) test

Your child will have rubber or foam plugs placed in the entrance of his/her ears during both tests. For the hearing test, his/her responses to sounds will be measured using age appropriate methods such as turning his/her head to a visual picture or object, completing a play-oriented task, or raising his/her hand. For the OAE testing, your child will be asked to sit still and quiet while sounds are played into his/her ears. Older children will be given the option of watching a silent movie during the test.

You or your child may choose to withdraw from the study at any time.

3. Expected costs:

There are no expected costs to you or your child for this study with the exception of travel to and from the Vanderbilt Bill Wilkerson Center.

4. Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

None of the test activities should be uncomfortable. Potential risks of participation include possible redness of the ear canal from the pressure of the earplug. Inconveniences include the time it takes to commute to the Vanderbilt Bill Wilkerson Center and to participate in the tests, if not tested in the NICU or newborn nursery.

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5. Unforeseeable risks:

There are no unforeseeable risks associated with participation in this study.

6. Compensation for participation:

For testing completed in the NICU or newborn nursery, compensation will be a developmentally appropriate book for an infant valued less than $5.00. Monetary compensation will be provided to children participants who are seen in our research laboratory at the Vanderbilt Bill Wilkerson Center on the 10th floor of Medical Center East in the form of a check mailed to you following the completion of a testing session. Checks are generally mailed within 4-6 weeks after you complete a test session. You will be paid $15.00 per hour for the test session upon completion of a test session. Completion of the test session is where useable information is obtained. You will be paid $15.00 for an incomplete test session since you had to travel to the test. A session is "incomplete" if no useable data is obtained for reasons including, but not limited to, your child being unable to complete any tests due to fussiness, or if the test must be stopped by the research investigator(s) for reasons such as equipment failure.

7. Circumstances under which the Principal Investigator may withdraw you from study participation:

Your child may be withdrawn from the study if you or your child indicates that you do not wish to participate. During testing your child must remain quiet and still. If complete data cannot be obtained in 2 sessions because the child is too noisy or active, your child will also be withdrawn.

For children under 7 years of age, before beginning testing we will read an assent script asking your child whether he/she agrees to participate. During the project, researchers will monitor for behavior indicating that your child no longer wishes to participate (e.g., refusing to cooperate, crying). If your child demonstrates such behavior, the procedures will be discontinued.

8. What happens if you choose to withdraw from study participation:

There is no penalty for withdrawing from the study. Your participation is voluntary. You can withdraw from the study at any time. If you would like to withdraw at the time of testing, tell any of the investigators you would like to stop the test. If you would like to withdraw your child in advance of the day of testing, contact Linda Hood at the number below, or by email linda.j.hood@vanderbilt.edu.

9. Contact Information:

If you should have any questions about this research study or possibly injury, please feel free to call the Principal Investigator**, (Linda J. Hood, Ph.D.)** at **(615-936-4612)**.

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10. Confidentiality:

All efforts, within reason, will be made to keep your child's personal information in your research record confidential but total confidentiality cannot be guaranteed. Information will be coded and stored in a locked file cabinet in a locked room of Dr. Hood's research laboratory. Only Dr. Hood and her approved research associates will have access to these files. Any information that is published will be in group form or completely without identifying information.

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STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

☐ **I agree to be contacted regarding future hearing studies for which my child may qualify.**

_____ _____
Date Signature of parent/guardian

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title