University of North Texas Health Science Center
Fort Worth, TX

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: [redacted]

PROTOCOL NUMBER: [redacted]

SPONSOR: [redacted]

Principal Investigator: [redacted]

Collaborating Investigators: [redacted]

SITE(S): [redacted]

STUDY-RELATED [redacted]

This is a research study consent form which may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Subjects Initials _____
Date _____

[redacted]

SUMMARY

- You are being asked to be in a research study.
- Your decision to be in this study is voluntary.
- If you decide to be in this study and then change your mind, you can leave the study at any time.
- You will be in this study for about two (2) weeks and have three (3) study visits including this visit.
- If you agree to be in this research study, your medical records will become part of this research. They will be looked at or copied by the four (4) investigators in this study, the sponsor of this study ([redacted]) or by government agencies or other groups responsible for the study, including review boards, or as federal law or regulations require.
- Your medical insurance will be billed for standard medical care that you receive as a part of this research study as well as for your treatments. Your insurance will not have access to the research records. Your insurance company may not pay for treatment associated with a research study. If your insurance company chooses not to pay for your participation, no charge will be made to you for participating in this research study.

More detailed information about this study is in this consent form. Please read it carefully.

PURPOSE OF THE STUDY:

The purpose of the study is to compare 2 slightly different head positions as they are performed in the Epley [canalith (head) repositioning] maneuver.

The Epley (canalith repositioning) maneuver allows the movement of symptom causing normally occurring but loosened (not attached) calcium carbonate otoconial crystals to be removed from the position-sensitive posterior semicircular canal (one of the parts of your ear that controls balance) into the less sensitive utricular area of the inner ear. Prior to the current study, measurements of the accuracy of Epley maneuvers were done by a physician and medical persons, and showed wide variation in consistency and accuracy of Epley maneuver performance.

The current study compares the Epley maneuver deviation identified in that study with an Epley maneuver performance as it was originally described by Dr. John Epley.

In this study, the consistency of the Epley maneuvers is controlled by using a goggle device. Using the goggle allows a visual feedback to the Epley maneuver performer such that the doctor can perform a more consistent and accurate Epley maneuver. In the first method of this study, the Epley maneuver guidance goggles have been set to best Epley maneuver performance practice as described by Dr. Epley. In the second method, the set of goggles have been set to the outer range of performance of measured Epley maneuver performance. That is to say, your maneuver may be done as accurately as an expert or as inaccurately as the least active measured Epley performed.

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[redacted]

You cannot choose if you will use the expert or the non-expert goggle method. This is decided by chance as by flipping a coin). You will have an equal chance of having expert versus non-expert Epley performance. You will not know which Epley maneuver method was used for you.

You will be in this study for approximately 2 - 5 weeks. Not more than 100 subjects will participate in this study across all study sites.

PROCEDURES

The following tests and procedures will be done during evaluation of your vertigo/dizziness/imbalance.

1. Physical examination (first visit).
2. Audiogram (first visit).
3. Electronystagmogram or video nystagmogram (balance test).

Tests listed below are 2 modifications of the standard medical practice Epley (canalith repositioning) maneuver.

1. Video recorded Hallpike (another type of head movement) maneuver.
2. Expert and non-expert goggle guided Epley maneuvers.

RISKS AND DISCOMFORTS

The most serious possible side effect of this study is slower improvement in your positional vertigo symptoms of approximately 1 week.

Note that your benign paroxysmal positional vertigo may not get better or may get better more slowly while you are in the study. In general, you may expect increased dizziness during the head maneuver (caused by the crystals moving within your inner ear). Also, during the head maneuver and the increased dizziness, some patients have reported nausea. If your symptoms are severe, ask your physician to give you medicine to suppress any nausea or vomiting before your head maneuver. In some cases, there may be a worsening of dizziness for 1-2 days.

BENEFITS

Your positional vertigo may improve as a result of your participation in this study; however, there is no guarantee of this. Other than that, there are no direct benefits to participating in this study. There is also some possible general benefit (to others) if we obtain a better understanding of how to treat positional vertigo.

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Date _____

[redacted] [redacted]

COSTS

There are no charges for the study treatments. Normal medical procedures for the evaluation and determination of diagnosis of positional vertigo will be billed to your insurance company.

PAYMENT FOR PARTICIPATION

Because of the short duration, lack of risks and patient treatments, we will not pay you to participate in this study (no subject fee). You will not be charged for your treatments during the period of study.

ALTERNATIVE TREATMENT

If you decide not to enter the study there are other treatments available. You can be treated by a standard Epley maneuver or you may seek treatment with another doctor. Whether or not you decide to participate in this study, the decision is totally up to you and will have no impact on your treatment or care by the study doctor.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get information and why they are able to get it. The study doctor must get your authorization (permission) to use or give out any health care information.

What information may be used and given to others?

If you choose to be in this study, the study doctor will get personal information about you; this information will include information that will identify you. Your doctor will also have information about your health including past and present medical records, research records, and records about phone calls. The research records will include information about your study visits, physical examination, balance test, and diary and questionnaire answers. There will be records also about the study devices.

Who may use and give out information about you?

You have been asked to take part in a research study. The researchers also need your permission (authorization) to use health information about you that is created by or used in connection with the research. If you are signing on behalf of someone other than yourself, this permission applies to that person's health records.

Subjects Initials _____

Date _____

[redacted]

Authorization to Use Health Information:

The investigator(s) named above and their assistants will be allowed to see and to use your health information for this research study. We may share your health information with people at the University of North Texas Health Science Center who help with the research. To do the research, we need to collect health information that identifies you. For you to be in this research, we need your permission to collect and share this information.

Term of Authorization:

If you sign this form, we will collect your health information until the end of the research. We may collect some information from your medical records even after your direct participation in the research project ends. We will keep all the information as long as necessary, in case we need to look at it again. We will protect the information and keep it confidential.

What if I decide not to give permission to use and give out my health information?

If you sign this form, you are giving us permission to collect, use and share your health information. You do not need to sign this form. If you decide *not* to sign this form, you cannot be in the research study. You need to sign this form if you want to be in the research study. We cannot do the research if we cannot collect, use and share your health information.

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to [redacted] listed on the consent form at [redacted] The letter needs to say that you have changed your mind and do not want Dr. [redacted] to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Who might get this information?

The four doctor investigators will be given your health information for their study.

Information about you and your health would only be given to the below listed agencies, as the Law requires.

1. US Food and Drug Administration (FDA).
2. Department of Health and Human Services (DHHS).
3. University of North Texas Health Science Center Institutional Review Board (UNTHSC-IRB). The UNTHSC-IRB is a group of people who perform individual review of research as required by regulations.

Subjects Initials _____
Date _____

Why will this information be used and/or given to others?

Information about you will be given to the participating physicians. The sponsor will analyze and evaluate the results of the study, but without individual identifying information.

The information may be given to the FDA, but will only be done as Law requires.

Results of this research maybe published in scientific journals or presented to medical meetings, but your identity will not be disclosed.

Is my health information protected after it has been given to others?

Your health information will be given to no one, but the participating physician or government agencies as is required by Law.

Questions regarding your privacy rights:

Any questions? Please ask the researcher (their phone numbers are listed on the first page of this form). You can also call Dr. Brian Gladue, Chairperson of the UNTHSC Institutional Review Board at 817-735-0409 with questions about the research use of your health information. The researcher will give you a signed copy of this form.

COMPENSATION FOR INJURY

In this study the risk of injury is very low. If the Epley maneuver causes you significant vertigo, contact your study doctor immediately. Medical treatment will be provided by the study doctor. Your insurance will be billed for such treatment. The sponsor will pay for charges that your insurance does not cover. No other compensations are available.

By signing this consent form you do not give up any legal rights.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by your study doctor or the sponsor without your consent because:

- the study doctor thinks it necessary for your health or safety;
- you have not followed study instructions;
- the sponsor has stopped the study; or
- administrative reasons require your withdrawal.

If you leave the study before the final regularly scheduled visit, you may be asked by your study doctor to make a final visit for some of the end of study procedures.

SOURCE OF FUNDING FOR THE STUDY

The study doctors' (the investigators) expenses are being paid by a National Institutes of Health (NIH) SBIR Grant to [redacted] Inc. You should also know that Dr. [redacted] has a significant financial interest in [redacted], Inc. and in the development of the device used in this study as well as data derived from this research study.

FINANCIAL DISCLOSURE

The results of this research project might be valuable for commercial purposes. Dr. [redacted] and [redacted]. may use information provided in this research study as part of an effort to develop a medical device, diagnostic test or other commercial application. In so doing, Dr. [redacted]. may decide to cooperate with other research companies or organizations for the same reasons. There is no program in place to compensate you with respect to any commercial activities related to your involvement in this study or the information you provide. Dr. [redacted]. retain sole ownership of the research results, and of any use or development of the research results.

QUESTIONS

If you have any questions about the study, you are free to contact Dr. [redacted] If you have questions about your rights as research subject, you may contact;

UNTHSC Institutional Review Board
3500 Camp Bowie Blvd, Fort Worth, TX 76107
Telephone 1-817-735-0409

Do not sign this consent form unless you have chance to ask questions or read and received satisfactory answers to all your questions.

Subjects Initials _____
Date _____

CONSENT

I have read the information in this consent form (or it has been read to me). All my questions about the study and my participation in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

_____
Subject Name

CONSENT SIGNATURE:

_____ _____
Signature of Subject Date

_____ _____
Signature of Person Conducting Informed Consent Discussion Date