Ascension

Ascension Providence Hospital
Southfield Campus, Novi Campus

The Use of Medical Grade Honey in the Prevention of Bone Anchored Hearing Aid Associated Skin Breakdown

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The Use of Medical Grade Honey in the Prevention of
Bone Anchored Hearing Aid Associated Skin Breakdown

Ascension Providence Hospital, Novi Campus
47601 Grand River Avenue, Novi, MI 48374

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY
and
AUTHORIZATION TO USE OR DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH (HIPAA)

Principal Investigator: Seilesh Babu, MD

Office Phone: (248) 865-4444

Please read the following material to ensure that you are informed of the nature of this clinical research study and how you will participate in it. Signing this form will indicate that you have been informed and that you give your consent to participate in a free manner. Federal regulations require written informed consent prior to participation in this clinical research study.

Introduction

This is an important form. Please read it carefully. It tells you what you need to know about this research study. If you agree to take part in this study, you need to sign this form. Your signature means that you have been told about the study and what the risks are. Your signature on this form also means that you want to take part in this study. Your study doctor will explain the research study to you. Research studies include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

You are being asked to take part in this research study because you are getting bone anchored hearing aid implant surgery at Ascension Providence Hospital, Novi Campus.

Why is this research being done?
Medical grade honey has recently became widely used and research continues to prove its strong antimicrobial effects. Medical grade honey is currently used across medicine for burns, wound infections, skin ulcers and more. One study previously looked at the use of honey to treat bone anchored hearing aid associated skin infections and saw a decrease in healing time from 5.25 weeks with just antibiotics, to 2 weeks with the addition of Medihoney.

Bone anchored hearing aids (BAHAs) implantation is a common otologic operation done today. Skin problems are the most common type of complication after this surgery; these can occur due to skin breakdown from the abutment or soft tissue infection.

This research is being done to determine if skin complications from bone-anchored hearing aids can be decreased with medical grade honey. The researchers will compare two different groups. You will be randomized (put into one group by chance). Your chances of being in one group are 1 in 2, like flipping a coin.

How many people will take part in this study?
Approximately 25-50 patients will be in this study.

How long will I be in this study?
You will participate in this study for 6 months. You will be seen in clinic 1-week post-op, 1-month post-op, 3 months post-op and 6 months post-op. Your part in the study is completed once you come to your 6-month postoperative visit.

What will happen if I take part in this research study?
This research will involve the application of medical grade honey to the bone anchored hearing aid abutment site for 2 weeks after surgery.

Immediately after surgery, MediHoney will be applied to the abutment site. The healing cap will be placed over the BAHA abutment site. The healing cap will be removed on postoperative day 7. You will be instructed to MediHoney daily to the area for 2 weeks. You will be seen in clinic 1-week post-op, 1-month post-op, 3 months post-op and 6 months post-op. During each visit the BAHA site will be examined for any skin breakdown. Photo documentation will be made of all cases and the photos will be reviewed by a blinded third party.

What are the risks of the study?

Infection is a possible risk to this study. If you develop an infection, it will be treated promptly with proper antibiotics. There is also a risk of adverse skin reaction to the medical grade honey. This is rare. If you have a history of adverse reactions to honey you will be excluded from the study. Every effort will be made to minimize any discomfort and these risks. If you do develop a reaction to the honey, we will immediately stop using it. You should tell the person obtaining your consent if you are currently participating in any other medical research studies.

What are the benefits of the study?

There may be no direct benefit to you in participating in the study. It is possible that you may heal quicker from the surgery and have less of a risk of infection or skin breakdown. In the future, other patients may benefit from the results of this study, when they become known.

What other options are there?

One option is to not participate. You do not have to participate in this research study in order to have a bone anchored hearing aid implant.

Do I have to participate in this study?

Your participation in this study is voluntary. Your refusal to participate will cause no penalty or loss of benefits which you would otherwise receive. If you decide to participate, you may change your mind about being in the study, and may quit at any time without penalty of loss of benefits regarding your future care. If new information becomes available during the study that may affect your willingness to continue in the study, your doctor and/or his/her associate will discuss this information with you. Also, your doctor may stop your participation at any time if he/she feels it is in your best interest. If this happens, you may be asked to return for a follow-up visit.

Will it cost anything to participate?

We do not expect there to be any additional costs to you if you participate in this study. Items related to the routine medical care that you would receive even if you did not participate in this study will be billed to you or your insurance company. You have the right to ask what it will cost you to take part in this study.

Will I be paid to participate?

There will be no compensation to you for your participation in this study.

Confidentiality of Records

The principal investigators will have access to your medical records and your test results. While absolute confidentiality cannot be guaranteed, all research material which could identify you will be kept as confidential as possible within the state and federal laws. You should be aware that your medical records could be examined by the sponsor, the Institutional Review Board (a group of people who review the research to protect your rights), or government agencies in order to verify the data collected during this research study. If the results of this study are presented in any public forum, you will not be personally identified.

What if I am injured?

There is no compensation or pay offered for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this study. You are not giving up any of your legal rights by signing this consent form.

Who do I call with questions about the study or to report an injury?

If you have any questions regarding a research-related injury, you can contact:
Dr. Seilesh Babu at the Michigan Ear Institute at 248-865-4444.

If you have any questions about your rights as a participant in this clinical research study, you may contact the IRB representative at 248-849-8889 at Ascension Providence Hospital Southfield Campus, Novi Campus.

Participant HIPAA Authorization to Use and Disclose Protected Health Information (PHI)

Your participation in this study will require the use and disclosure of certain medical and other information about you. The information that may be used or disclosed includes: any and all health care records such as: laboratory, pathology and/or radiology results; scans; x-rays; and Protected Health Information (PHI) previously collected for research purposes.

Your PHI will be used in the following ways: To conduct the research and to ensure that the research meets legal, institutional or accreditation requirements.

Your authorization to use and disclose the above information has no expiration date.

Your PHI may be seen, used or disclosed to the following:

- ☒ The researchers and members of the research team.
- ☐ The sponsor, *(insert Sponsor's name)* and/or a clinical research organization or other agent of the sponsor.
- ☐ A laboratory outside of Ascension Providence Hospital.
- ☒ Other health care providers or employees of Ascension Providence Hospital who provide services to you for this study.
- ☒ Representatives of the Institutional Review Board (IRB), the FDA (Food and Drug Administration), or other governmental agencies involved in research monitoring.
- ☐ Members of a safety monitoring board.
- ☐ Other agencies as required by law.

You have the right to review your PHI. However, if you agree to participate in the research study and sign below, you will not be able to look at your research information until the research study is completed.

You do not have to sign this authorization. If you decide not to sign the authorization it will not affect your treatment or eligibility for health benefits. However, if you do not sign this authorization you may not participate in this study.

You may withdraw your authorization at any time by notifying the principal investigator in writing, but the withdrawal will not affect any information already disclosed. However, you need to be aware that your written withdrawal of this Authorization may result in the termination of the research-related treatment being provided to you.

Seilesh Babu, MD
Michigan Ear Institute
30055 Northwestern Highway, #101
Farmington Hills, MI 48334

When you sign this authorization, your health information may be re-disclosed by the researcher if permitted or required by applicable federal or state law.

CONSENT

You have had the opportunity to fully discuss the purpose of this clinical research study and how it will be carried out. Your questions have been answered. Your participation in this study is fully voluntary and you may withdraw at any time.

Your signature below acknowledges that you voluntarily agree to participate in this clinical research study, and you will receive a signed copy of this form.

_____

Printed Name of Research Participant

_____ _____

Signature of Research Participant Date

Legally Authorized Representative (if applicable):

_____
Printed Name of Legally Authorized Representative

_____ _____
Signature of Legally Authorized Representative Date

Check Relationship to Participant:*

☐ Legal Guardian or Legally Authorized Representative for Medical Care (LARM) ☐ Spouse
☐ Adult Son or Daughter ☐ Mother or Father ☐ Adult Brother or Sister ☐ Other, explain:

Reason participant is unable to sign for self:

**If a Legal Guardian or Legally Authorized Representative for Medical Care (LARM) has not been appointed, then consent should be obtained from the closest next of kin (in the order listed above). When that individual is unavailable or refuses to act the next in order should be contacted.*
** If there is a disagreement among next of kin regarding the appropriateness of the treatment plan, Clinical Safety Risk Management may be contacted. Outside of business hours, Clinical Safety Risk Management can be contacted through any Ascension Providence Hospital operator.*

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

Use the following only if applicable.

If this consent form is read to the participant because the participant is unable to read the form, an impartial witness, not affiliated with the research study or investigator, must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by the participant. The participant freely consented to be in the research study.

_____

Printed Name of Impartial Witness

_____ _____

Signature of Impartial Witness Date

Note: This signature block cannot be used for translations into another language. An IRB-approved translated consent form is necessary for enrolling participants who do not speak English.