PROTOCOL TITLE:

Antibiotic concentration after delivery to middle ear for chronic suppurative otitis media

STUDY IDENTIFIERS:

NCT ID not yet assigned
Unique Protocol ID: STUDY02001093

PRINCIPAL INVESTIGATOR:

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VERSION NUMBER/DATE:

Version 1 (updated as of July 13, 2021)

*Dartmouth-Hitchcock (D-HH HRPP) IRB approval for this consent form is effective from July 7, 2021, until July 21, 2022.

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	July 13, 2021	No changes – version 1 uploaded to IRB portal	

Title of research study:

Measuring antibiotic solution concentration at the tympanic membrane following self-administration by patients with chronic otorrhea.

Investigator: Dr. James E. Saunders

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are experiencing chronic suppurative otitis media (CSOM).

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this study is to develop methodology to better understand the potential effect of ototopical antibiotic concentration on clinical outcomes in patients with chronic middle ear infections. We will do so by measuring antibiotic concentrations in aspirates from the middle ear of selected patients with otorrhea due to Chronic Suppurative Otitis Media (CSOM) who are prescribed and instructed to self-administer ototopical ciprofloxacin.

How long will the research last and what will I need to do?

We expect that you will be in this research study for a maximum of 3 months.

Before leaving the clinic today, you will be given a prescription of antibiotic drops of ciprofloxacin 0.3% and dexamethasone 0.1% suspension with specific written instructions for administering droplets three times daily for ten days. Afterwards, you will be asked to return between 3 to 10 days after the initial visit. Additionally, you will be asked to keep a log of medication and to apply the droplets 1 hour before your follow-up appointment.

During this visit, your affected ear will be cleaned of any wax or purulent debris. Then, a microscopic aspirate (~100 μL) will be collected using with a modified Juhn Tym-Tap®. After sampling, the volume of the aspirate will then be precisely measured with a device developed specifically for this study. The color and consistency of the sample will be noted. The sample will then be diluted with a known volume of water to an acceptable volume for the LC-MS/MS assay. Additional data including otologic diagnosis, bacteria culture results, presenting symptoms, specific site of infection, external ear canal volume estimates (based upon tympanometry and physical exam), configuration of external auditory canal, prescribed treatment, treatment outcome, and duration of infection will be recorded for our analysis.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

There are minimal risks to this study, which include minimal physical discomfort when aspirating the fluid from your ear in clinic, potential stress from pressure to comply to research protocol, and time invested for additional visits and completing the medication compliance log.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include a better understanding of the effect of ototopical antibiotics on the clinical outcomes of patients, such as yourself, suffering from chronic middle ear infections. To offset the potential economic burden, subjects will be compensated $50 for their participation.

What happens if I do not want to be in this research study?

Participation in research is completely voluntary. You can decide to participate or not to participate.

Your alternative to participating in this research study is to not participate.

The standard antibiotic treatment for chronic otitis media used in this study is available to you whether or not you take part in the study.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team:

James E. Saunders, MD FACS

James.E.Saunders@hitchcock.org

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (603) 650-1846 or irb@hitchcock.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be in this study?

We expect about 10 people with CSOM to participate in this research study.

What happens if I say yes, I want to be in this research study?

If you agree to participate in this study, you will do your best to follow medication instruction of administering ototopical antibiotic droplets three times daily for ten days, which is the standard of care for COSM that you will have the option of receiving regardless of your choice to participate in this study.

As part of the research study, you will additionally accomplish the following research measures. You will be asked to fill out a compliance log during the entire duration of your participation. Furthermore, you are asked to return to the Dartmouth-Hitchcock ENT clinic (4F) for a follow-up visit 3 to 10 days after the initial visit with an application of droplets 1 hour prior. During this visit, a small device called the Juhn Tym-Tap device will be used to aspirate middle ear fluid for analysis. Furthermore, a thorough physical exam (especially that of the ear) will be done. If symptoms do not resolve within the ten days, weekly telephone surveys regarding symptoms will be done until symptoms resolve, new treatment is prescribed, or a maximum duration of three months of follow-up.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you. This will not affect your treatment. If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Is there a possibility being in this study could be bad for me or harm me? (Detailed Risks)

As mentioned above, there are minimal risks to this study, which include minimal physical discomfort when aspirating the fluid from your ear in clinic, potential stress from pressure to comply to research protocol, and time invested for additional visits and completing the medication compliance log. The

antibiotic formula given during this research study is the standard of care for CSOM. There is a chance that your infection may not improve, in which case we will manage accordingly.

Local Information: If you are injured or become ill as a result of research procedures, you will be provided with medical treatment but the following organizations do not plan to pay for this treatment.

- Mary Hitchcock Memorial Hospital
- Dartmouth-Hitchcock Clinic
- Dartmouth-Hitchcock Medical Center
- Trustees of Dartmouth College
- Federal funding agency

If you have any questions or concerns about the legal responsibility of these organizations, please call the Mary Hitchcock Memorial Hospital Office of Risk Management at (603) 653-1250 during normal business hours.

If you agree to take part in this study and you sign this consent form, you are not giving up any of your legal rights.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Federal law provides additional protections of your medical records and related health information. By signing this form, you allow the research team to use your health information and give it to others involved in the research. The research team includes the study director plus others working on this study at Dartmouth-Hitchcock Medical Center and elsewhere. You also permit any health care provider holding health information needed for this study to give copies of your information to the research team.

The information collected for this study may be used by researchers or officials of the following institutions.

- Dartmouth College
- Mary Hitchcock Memorial Hospital
- Dartmouth-Hitchcock Clinic
- Dartmouth-Hitchcock Medical Center
- The Dartmouth-Hitchcock Health Institutional Review Board (D-HH IRB)

In order to conduct this study, researchers need to use your health care information. This data is called Protected Health Information ("PHI"). PHI is protected by federal privacy laws (HIPAA). By signing this consent form, you give your permission to have your PHI collected, used and disclosed for purposes of this study. There is no intention to disclose your PHI to others outside of the study. There are protections in place to keep your PHI and research data confidential. However, HIPAA requires

notification so you are aware that if your PHI is disclosed to others, it may no longer be protected by federal privacy laws.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Identifiable data collected for this study will be used for research purposes which are determined to be reasonable and in line with expectations by a review committee.

Once data collected for this research study is no longer identifiable, the data may be used or disclosed for other purposes.

Your permission to use your health information for this study will not end until the study is completed. During this study, you and others who take part in the study may not have access to the study data. You may ask for study data once the study is over. You have a right to receive a copy of the information in your medical record at any time.

Your name, address, and social security number may be given to an office at DHMC that arranges for payments and reports payments to the IRS.***

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include misdiagnosis, noncompliance with antibiotic medication, failure to follow up.

What else do I need to know?

If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party. Dartmouth Hitchcock Medical Center has no program to pay for medical care for research-related injury.

If you agree to take part in this research study, we will pay you $50 for your time and effort.

Instead of being in this research study, your choices may include: not participating. Your treatment will not be altered by not participating in this study.

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers ***will*** contact you to let you know what they have found

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	7/27/21 to 7/21/22 IRB Approval Date