

Patient Satisfaction in Mohs
Micrographic Surgery with
Supplemental Lidocaine Jelly

NCT03595449

1/21/2018



IRB Minimal Risk Protocol Template

Note: If this study establishes a human specimen repository (biobank) for research purposes, do not use this template. Use the Mayo Clinic Human Specimen Repository Protocol Template found on the IRB home page under Forms and Procedures at <http://intranet.mayo.edu/charlie/irb/>

First-time Use: Use this template to describe your study for a new IRB submission.

1. Complete the questions that apply to your study.
2. Save an electronic copy of this protocol for future revisions.
3. When completing your IRBe application, you will be asked to upload this document to the protocol section.

Modification: To modify this document after your study has been approved:

1. Open your study in IRBe. Click on the study 'Documents' tab and select the most recent version of the protocol. Save it to your files.
2. Open the saved document and activate "Track Changes".
3. Revise the protocol template to reflect the modification points, save the template to your files
4. Create an IRBe Modification for the study and upload the revised protocol template.

General Study Information

Principal Investigator: Shari Ochoa, MD

Study Title: Patient Satisfaction in Mohs Micrographic Surgery with Supplemental Lidocaine Jelly

Protocol version number and date: Version 1, January 21, 2018

Research Question and Aims

Hypothesis: Supplementing lidocaine/epinephrine injections with intralesional lidocaine jelly will decrease the overall quantity of lidocaine/epinephrine injectable used, and will decrease patients' self-reported pain/anxiety associated with needle sticks.

Objectives: To assess how using lidocaine jelly in Mohs surgery impacts 1) the overall quantity of lidocaine/epinephrine injectable needed to maintain anesthesia, and 2) patients' pain/anxiety associated with anesthesia injections.

Background:

Mohs micrographic surgery is a procedure that removes cancerous lesions of the skin in a step-wise fashion. Patients are injected with local analgesia for tumor extirpation. The tumor is removed and the tissue is sent for histopathology while the patient waits. Tissue processing time can take up to 2 hours during which the effects of the local analgesia have waned. Once the tissue has been process and examined, patients are brought back to the surgical suite and either have another section of tissue removed (if the margins were positive) or have the wound reconstructed (if the margins were negative). Lidocaine Hydrochloride (Xylocaine) injection with



Epinephrine is the traditionally method used to maintain local anesthesia throughout the procedure. The FDA has declared a shortage of this injectable Lidocaine/Epinephrine, stressing the need for a substitute drug. Additionally, multiple needle sticks can be uncomfortable and anxiety provoking for patients. Needle sticks on hypersensitive areas such as the nose can be particularly painful. Previous research has demonstrated that a different form of anesthetic, a topical lidocaine jelly, is efficient in prolonging anesthesia in Mohs surgery (Robins, 1991). No study has published the impact of supplemental lidocaine jelly use on the overall quantity of injection needed, nor on patient pain/anxiety associated with needle sticks.

Study Design and Methods

Methods:

We will conduct a prospective, randomized trial of 250 patients receiving Mohs micrographic surgery to lesions on the nose. Annually Mohs micrographic surgery is performed on approximately 900 patients with 30% of these procedures being performed on lesions on the nose. Patients receiving Mohs treatment for lesions on the nose will be randomly assigned to one of two groups: (1) those whose wounds will be dressed with lidocaine jelly (treatment group), and (2) those whose wounds will be dressed with surgical lubricant (control/placebo group).

All patients will receive a pre-treatment baseline pain/anxiety survey followed by an initial lidocaine injection. The amount of lidocaine/epinephrine injection each patient receives throughout remaining stages of surgery will be recorded, as per the current workflow. All patients will complete a second pain/anxiety survey immediately after numbing but prior to the first stage of surgery.

After the first stage of surgery, either lidocaine jelly or surgical lubricant will be applied to the wound followed by a pressure bandage as per standard practice. Dressing are removed immediately prior to the next stage of surgery. After each subsequent stage of surgery, an identical wound dressing will be placed on the operative site.

Immediately prior to each subsequent stage of surgery, we will assess patients' pain sensation, and additional lidocaine/epinephrine will be injected if needed. After the surgical site is re-anesthetized, vital signs will be recorded and the Pain/Anxiety survey administered immediately prior to the first incision of that stage.

Resources:

Biostatistician [REDACTED], PhD will perform statistical analyses.

Subject Information

Target accrual is the proposed total number of subjects to be included in this study at Mayo Clinic. A "Subject" may include medical records, images, or specimens generated at Mayo Clinic and/or received from external sources.



Target accrual: 250

Subject population (children, adults, groups): males and females ages 18 and older

Inclusion Criteria: Patients undergoing Mohs surgery anywhere on the nose.

Exclusion Criteria: Patients undergoing multiple Mohs surgeries in different anatomic locations on the same day (nose and ear, etc.). Patients who are unable to consent to the study or who are unable to complete the questionnaire. Patients with allergy to lidocaine.

Research Activity

Check all that apply and complete the appropriate sections as instructed.

1. ☒ **Drug & Device:** Drugs for which an investigational new drug application is not required. Device for which (i) an investigational device exemption application is not required; or the medical device is cleared/approved for marketing and being used in accordance with its cleared/approved labeling. (Specify in the Methods section)
2. ☐ **Blood:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
3. ☐ **Biological specimens other than blood:** Prospective collection of human biological specimens by noninvasive means that may include: urine, sweat, saliva, buccal scraping, oral/anal/vaginal swab, sputum, hair and nail clippings, etc.
4. ☐ **Tests & Procedures:** Collection of data through noninvasive tests and procedures routinely employed in clinical practice that may include: MRI, surface EEG, echo, ultrasound, moderate exercise, muscular strength & flexibility testing, biometrics, cognition testing, eye exam, etc. (Specify in the Methods section)
5. ☒ **Data** (medical record, images, or specimens): Research involving use of existing and/or prospectively collected data.
6. ☐ **Digital Record:** Collection of electronic data from voice, video, digital, or image recording. (Specify in the Methods section)
7. ☒ **Survey, Interview, Focus Group:** Research on individual or group characteristics or behavior, survey, interview, oral history, focus group, program evaluation, etc. (Specify in the Methods section)

☐ NIH has issued a *Certificate of Confidentiality (COC)*. When checked, provide the institution and investigator named on the COC and explain why one was requested. _____



Biospecimens – Categories 2 and 3

(2) Collection of blood samples. When multiple groups are involved copy and paste the appropriate section below for example repeat section b when drawing blood from children and adults with cancer.

- a. **From healthy, non-pregnant, adult subjects who weigh at least 110 pounds.** For a minimal risk application, the amount of blood drawn from these subjects may not exceed 550ml in an 8 week period and collection may not occur more frequently than 2 times per week.

Volume per blood draw: _____ ml

Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.) _____

- b. **From other adults and children considering age, weight, and health of subject.** For a minimal risk application, the amount of blood drawn from these subjects may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period, and collection may not occur more frequently than 2 times per week.

Volume per blood draw: _____ ml

Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.) _____

(3) Prospective collection of biological specimens other than blood: _____

Review of medical records, images, specimens – Category 5

For review of existing data: provide a date range or an end date for when the data was generated. The end date can be the date this application was submitted to the IRB. Example: *01/01/1999 to 12/31/2015* or all records through *mm/dd/yyyy*.

Date Range:

Check all that apply (data includes medical records, images, specimens).

☐ (5a) Only data that exists before the IRB submission date will be collected.

☐ (5b) The study involves data that exist at the time of IRB submission **and** data that will be generated after IRB submission. Include this activity in the Methods section.

Examples

- The study plans to conduct a retrospective chart review and ask subjects to complete a questionnaire.
- The study plans to include subjects previously diagnosed with a specific disease and add newly diagnosed subjects in the future.



☐ (5c) The study will use data that have been collected under another IRB protocol. Include in the Methods section and enter the IRB number from which the research material will be obtained. *When appropriate, note when subjects have provided consent for future use of their data and/or specimens as described in this protocol.*

Enter one IRB number per line, add more lines as needed

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ (5d) This study will obtain data generated from other sources. Examples may include receiving data from participating sites or an external collaborator, accessing an external database or registry, etc. Explain the source and how the data will be used in the Methods section.

☐ (6) Video audio recording: *Describe the plan to maintain subject privacy and data confidentiality, transcription, store or destroy, etc.*



HIPAA Identifiers and Protected Health Information (PHI)

Protected health information is medical data that can be linked to the subject directly or through a combination of indirect identifiers.

Recording identifiers (including a code) during the conduct of the study allows you to return to the medical record or data source to delete duplicate subjects, check a missing or questionable entry, add new data points, etc. De-identified data is medical information that has been stripped of all HIPAA identifiers so that it cannot be linked back to the subject. De-identified data is **rarely** used in the conduct of a research study involving a chart review.

Review the list of subject identifiers below and, if applicable, check the box next to each HIPAA identifier being recorded at the time of data collection or abstraction. Identifiers apply to any subject enrolled in the study including Mayo Clinic staff, patients and their relatives and household members.

Internal refers to the subject's identifier that will be recorded at Mayo Clinic by the study staff.

External refers to the subject's identifier that will be shared outside of Mayo Clinic.

Check all that apply:	INTERNAL	EXTERNAL
Name		
Mayo Clinic medical record or patient registration number, lab accession, specimen or radiologic image number	X	
Subject ID, subject code or any other person-specific unique identifying number, characteristic or code that can link the subject to their medical data	X	
Dates: All elements of dates [month, day, and year] directly related to an individual, their birth date, date of death, date of diagnosis, etc. Note: Recording a year only is not a unique identifier.	X	
Social Security number		
Medical device identifiers and serial numbers		
Biometric identifiers, including finger and voice prints, full face photographic images and any comparable images		
Web Universal Resource Locators (URLs), Internet Protocol (IP) address numbers, email address		
Street address, city, county, precinct, zip code, and their equivalent geocodes		
Phone or fax numbers		
Account, member, certificate or professional license numbers, health beneficiary numbers		
Vehicle identifiers and serial numbers, including license plate numbers		
Check 'None' when none of the identifiers listed above will be recorded, maintained, or shared during the conduct of this study. (exempt category 4)	<input type="checkbox"/> None	<input checked="" type="checkbox"/> None



Data Analysis

Power analyses may not be appropriate if this is a feasibility or pilot study, but end-point analysis plans are always appropriate even if only exploratory. Provide all information requested below, or provide justification if not including all of the information.

Power Statement:

Power simulations were based on anticipated analysis of group differences via *t*-tests, Chi-square tests, and Wilcoxon rank-sum tests. These simulations suggested that enrollment of 250 total patients (125 each in control/placebo group and lidocaine jelly treatment group) would allow us to detect a moderate effect ($d = .5$, $w = .3$, and $d = .5$ respectively) of differences between groups at a significance level of $p < .05$ with power of 90% or greater in our planned analyses.

Data Analysis Plan: Primary analyses of interest are descriptive statistics for measures of pain, anxiety, biometric indicators (e.g., heart rate, blood pressure), and amount of total lidocaine administered by injection for each group. Secondary analyses will include statistical tests (e.g., *t*-tests, χ^2 , and Wilcoxon rank-sum) for comparison between control and treatment group for differences on pain, anxiety, and vital signs. Additional analysis of differences in pain/anxiety across repeated rounds of testing within groups will be explored given sufficient data via descriptive statistics, statistical test, and possible mixed models comparing changes over repeated rounds between groups (dependent on rates of patients with multiple-stage Mohs procedures).

Endpoints

Primary: patient pain/anxiety score as indicated by survey, and quantity of Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine

Secondary: Blood pressure and heart rate, any history of Mohs surgery (any location, any provider)