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Columbia University Human Subjects Protocol

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Title: Auriculotherapy as an adjunct for pain management during medication abortion: a randomized, double-blinded, three arm trial

Study Purpose and Rationale

The CDC reported 638,169 abortions in 2015; of these, 91% took place at 13 weeks' gestation (Jatlaoui, 2018). Because several large jurisdictions do not report abortion data to the CDC, the correct number of U.S. abortions is larger. Abortions are being performed earlier than ever, in large part due to approval and increasing use of medication abortion with mifepristone and misoprostol prior to ten weeks gestation. The evidence-based regimen used in the U.S. consists of oral mifepristone 200 mg, followed by misoprostol 800 mg, generally taken at home about 24-72 hours after the mifepristone. Most women undergoing medication abortion report moderate or severe pain that usually occurs during the six hours after using misoprostol. Analgesics for medication abortion typically include nonsteroidal anti-inflammatory drugs (ibuprofen), and sometimes opioids, but few studies have evaluated pain management in this setting (Westhoff, 2000). Investigations into the role of adjunct pain medications, specifically opioids and anxiolytics, have consistently found them ineffective for first trimester aspiration abortion pain (Micks, 2012; Bayer, 2015) and unnecessarily dispensing these medications contributes to the opioid epidemic, but analgesia for medication abortion has undergone limited evaluation. The National Academy of Sciences published "The Safety and Quality of Abortion Care in the U.S." highlighting the existing research gap in optimizing pain management during abortion (National Academy of Sciences, 2018), while the Society for Family Planning urged future investigators to focus on non-pharmacologic methods (Allen, 2018). Promising data suggest that acupuncture is a good adjunct for obstetric and gynecological pain (Borup, 2009; Smith, 2011; Kiran, 2013), which prompted us to carry out a randomized trial examining auricular acupuncture using Pyonex™ needles, as an adjunct to paracervical block and ibuprofen (usual care) (AAAR2610). That study revealed substantially lower pain and anxiety scores of women receiving auricular acupuncture compared to pain and anxiety scores of women receiving placebo or usual care alone during first-trimester vacuum aspiration (Ndubisi, 2018). These results are promising and might apply to pain management for medication abortion. Various state restrictions may limit provision of acupuncture with needles due to extensive training requirements (Lin, 2017). Auricular acupressure with beads showed labor pain reduction and may prove to be an effective alternative to acupuncture (Smith, 2011). Acupressure is not regulated to the same extent as acupuncture as it is non-invasive and without skin penetration. No studies, however, have examined acupressure in abortion pain management. Therefore, we propose a three-arm trial to assess maximum pain and anxiety scores during medication abortion with participants randomized to either (1) auricular acupressure with Acu-patch beads plus usual care, (2) auricular acupuncture with Pyonex™ needles plus usual care, or (3) placebo patches plus usual care. The goal of this study is to test the hypothesis that either auricular acupressure with beads, or with pyonex needles, in addition to usual care with ibuprofen will minimize pain during medication abortion up to 10 weeks gestation. Auricular acupuncture and auricular acupressure together constitute auriculotherapy. This study will take place in parallel with a trial to evaluate the same auriculotherapy interventions in women undergoing first trimester vacuum aspiration abortion (AAAS0917).

Study Design

Background: The proposed study will be a randomized, blinded, placebo-controlled, three-arm trial at a single abortion practice at CUIMC to evaluate the efficacy of auriculotherapy as an

adjunct to ibuprofen for management of pain and anxiety in patients undergoing a medication abortion with mifepristone and misoprostol at gestational age of less than 10 weeks. We will recruit patients from a single abortion practice at CUIMC with the expectation to recruit about 150 patients. We will randomize those who agree to participate to receive acupressure vs. acupuncture vs. placebo patches following completion of all usual care. Usual care includes obtaining vital signs, medical history, physical exam, ultrasonography, and collection of a blood sample for Rh status confirmation, and consent for the abortion treatment itself. Women receive the 200 mg dose of mifepristone during their clinic visit, and receive misoprostol 800 mcg (buccal) to use at home 24-72 hours after the mifepristone. All women also receive a prescription for ibuprofen 600 mg, #20, to take every 6 hours as part of their usual care and they receive a one-week follow-up appointment to evaluate treatment success and to initiate contraception (if desired). Patient-care sites for this study will include VC 10, HIP and 1790 Broadway.

Recruitment: After completion of all usual patient care activities and administration of the mifepristone tablet, the MD caring for the patient will offer the patient the opportunity to speak with the research assistant about participation in this auriculotherapy study. The research assistant will summarize the study and state the research objectives. The research assistant will then proceed with the informed consent process for interested patients who meet inclusion criteria. After informed consent, research assistants will collect demographic information and baseline characteristics into a preprogrammed electronic tablet from which all information will be transmitted directly into the study REDCap database. The research assistant will collect baseline pain and anxiety scores using 100 mm VAS pre-programmed into the same tablet.

Intervention: Participants will receive random assignment into one of the three study arms. The research assistant will give the next sequential opaque sealed envelope containing the treatment assignment to the auriculotherapy provider. All clinicians in our practice will be trained as part of an ongoing auriculotherapy study. The auriculotherapy provider will always be different from the research assistant and the abortion provider. The auriculotherapy provider will open the assignment envelope and enter the room without the research assistant or the abortion provider. Each auriculotherapy intervention provider will follow a script and will tell the participant that she “may or may not feel a sensation from the treatment”. After cleaning both ears with alcohol, the auriculotherapy provider will place the acupressure beads or the Pyonex™ needles, following the Gold protocol (see below). These treatments adhere to the ear with adhesive patches; participants in the placebo arm will receive placement of similarly sized adhesives. The adhesive patches are similar in size and appearance and thus the participants will not know which treatment they have received. The participants will go home wearing the auricular patches. Clinical use of acupuncture to treat chronic pain has demonstrated that these patches readily remain in place for a week or longer and do not detach with sleeping, showering or shampooing. During medication abortion, cramps and pain tend to occur after using misoprostol, which will take place about 1-3 days after the initial visit according to the patient’s preferred timing. To track patient pain and anxiety, we will send each patient a 2-way text message at 8pm for the next four days and ask her to respond with her maximum pain level during the previous 24 hours. Our research group has experience sending such text messages to patients to assess pain (Nippita, 2015), and has experience with using a text message with a web link to report pain scores using a VAS. For any patient who wants to participate in the study, but does not have a mobile phone with text and web capability, we will offer a paper diary to record pain and

anxiety. The research assistant will remind patients to return for the routine one-week follow-up appointment, and during that appointment the participants will again report their maximum pain and anxiety scores using VAS scales; they will also complete a satisfaction survey and identify the treatment arm they believe they received. The research assistant will remove the adhesive patches. The participant will receive thanks for participating in the study and \$25 for compensation.

Statistical Procedures

Number of subjects and statistical power: For this study we plan to recruit 5 patients a week to reach a total of 47 participants per treatment arm or 141 participants over approximately 30 weeks. Estimating an effect size of 20 mm with standard deviation of 30 (calculated from the prior acupuncture study), 80% power, a 5 % level of significance, and presuming 20% dropout after enrollment, the study will require 47 participants in each arm (141 participants altogether). Prior studies selected an effect size of 20 mm to evaluate non-pharmacologic pain management during first-trimester aspiration abortion (Tschan, 2018; Wang, 2018). Our recent acupuncture trial achieved a 30-point pain reduction in the treatment group compared to the placebo group (Ndubisi, 2018). In our clinics about 25% of patients do not return for follow-up after a medication abortion – we do not know if study participation will increase or decrease this loss to follow-up. We also do not know whether patients will respond to the text messaging, but in our previous study, text messaging response rates were excellent in a similar patient population (Nippita, 2015). Data Analysis: We will use descriptive statistics to report participant baseline characteristic including variables that may affect pain. Demographic information will include age, education, preferred language, BMI, race/ethnicity, illicit drug/alcohol use, anxiety or depression medication use in the last 30 days, and history of acupuncture use. Reproductive information will include dysmenorrhea history, parity and recency of last birth, gestational age, history of induced abortion vs. early pregnancy loss or management of abnormal pregnancy. We will compare demographic and baseline characteristics across the three groups with Chi-square tests for categorical variables and analysis of variance (ANOVA) for continuous variables in order to assess whether randomization was successful. The primary outcome will be maximum pain during medication abortion follow-up; we will assess the maximum reported pain on any of the four days following treatment initiation because women will vary in when they use the misoprostol and when they experience maximum pain. We will also evaluate maximum pain as reported during the follow-up visit. The primary analyses will compare acupressure vs. placebo, and acupuncture vs placebo; we will analyze the difference between the median subject-reported maximum pain score as measured by VAS among women randomized to receive usual care plus auriculotherapy (needles or beads) vs. usual care plus placebo. In the previous pilot study the VAS scores were not normally distributed (Ndubisi, 2018), therefore we will compare the medians, not means. Because the previous trial found a substantial reduction in median anxiety in the participants who received acupuncture, our secondary analysis will evaluate differences in the median anxiety score as measured by VAS across the three study arms. An exploratory analysis will compare acupuncture to acupressure; we will analyze the difference between the median subject-reported maximum pain score reported using VAS among women randomized to receive usual care plus auriculotherapy with needles (acupuncture) vs. usual care plus beads (acupressure). We will also compare participant global satisfaction using a satisfaction survey, and describe and compare participant identification of the treatment arm.

This will be an intention-to-treat analysis to maintain comparability of our treatment arms following randomization. Initial analyses will take place blinded to the treatment assignment in order to reduce bias in the analysis. Expecting that VAS scores will not be normally distributed, we plan to use non-parametric tests (Kruskal-Wallis and Mann-Whitney tests) to compare VAS pain and anxiety scores between the groups. A 20mm or greater reduction in maximum pain scores among participants receiving usual care plus auriculotherapy would uphold the primary hypothesis.

Confidentiality: Study records that identify subjects will be kept confidential as required by law. Subjects will receive a study subject number and this code will be used for most disclosures to identify the subject. All personnel who will collect input or otherwise handle data have been trained in Good Clinical Practice and HIPAA regulations with Columbia University. All data will be stored on a password protected fire walled, certified secure server at Columbia University, Department of Obstetrics and Gynecology. The PI will develop a database in Research Electronic Data Capture (REDCap) – a mature, secure web-based application for building and managing surveys and databases – that has been IRB-approved for use here at CUMC. This database will contain information from our screening documents and data. This database will be password-protected using a strong password and encrypted and access to it will be restricted to personnel listed on the study's IRB protocol. Data from REDCap will be uploaded to SPSS for data analysis.

Study Procedures

Subjects and recruitment: As stated above, we will recruit all participants from the sites that provide medication abortion care at CUMC – mainly VC 10, but also the practice at 1790 Broadway, in New York City, NY. We will invite women presenting for medication abortion to participate in the study after they have completed all routine care at the visit.

Inclusion criteria will be as follows:

- I. English or Spanish speaking women
- II. Age 18 and older
- III. Seeking medication abortion
- IV. With confirmed intrauterine pregnancy with measured gestational age less than or equal to 10 weeks and 0 days
- V. Willing to receive auriculotherapy
- VI. Willing to be randomized

Exclusion criteria will be as follows:

- I. Does not meet study criteria
- II. Allergy to adhesives
- III. Allergy to or unable to receive ibuprofen
- IV. Congenital anomaly or infection of the ear

After completing routine patient care, including abortion consent, the clinician will refer interested patients to the study research assistant. If a patient states interest in the study and

meets inclusion criteria, the research assistant will proceed with the informed consent process. After informed consent, research assistants will record demographic information and other baseline characteristics into a preprogrammed electronic tablet from which all information will be transmitted directly into the study REDCap database. The research assistant will collect baseline pain and anxiety scores using 100 mm VAS pre-programmed into the tablet. A VAS-P (pain) with anchors at 0 mm = no pain and 100 mm = worst pain in my life will be used to collect pain scores. A VAS-A (anxiety) with anchors at 0 mm = not at all anxious and 100 mm= worst anxiety of my life will be used to collect anxiety scores. The VAS is a validated pain scale measure often used to measure the intensity of pain and is also validated to measure anxiety (Facco, 2013; Renner, 2010).

Randomization and blinding: The participants will be randomized into one of the three interventions: 1 - usual care for pain management (i.e., ibuprofen) plus auricular acupressure with Accu-Patch beads, 2 - usual care plus auricular acupuncture with Pyonex™ needles, or 3- usual care plus similarly-sized adhesive patches. Usual care for pain management consists of a prescription for Ibuprfen 600mg #20, to use every 6 hours as needed. Patients do not receive narcotic analgesics. Prior to any recruitment, research staff not involved in participant recruitment will determine the 1:1:1 allocation in blocks of 6 using a random number table and will prepare the sequentially numbered, sealed, opaque envelopes. The auriculotherapy provider will open the assignment envelope and enter the room without the research assistant or the abortion provider. The auriculotherapy provider will not reveal the treatment assignment to the participant, abortion provider, research assistant, or clinical staff. The auriculotherapy provider will place the beads/needles/placebo patches bilaterally, out of view of the participant, and will inform the participant that she may or may not feel a sensation from the treatment in order to maintain subject blinding. The participant will then leave the clinic taking a one-week return appointment, a prescription for ibuprofen and the correct dose of misoprostol to use at home (all per routine care). **Auriculotherapy protocol:** For this study, auriculotherapy will be completed using the Gold protocol acupoints. The Gold protocol was used in the prior study (Ndubisi, 2018) and is a modified Battlefield Acupuncture protocol (BFA). The original BFA protocol developed by Richard C. Niemtzow, MD, PHD, MPH in 2001 in the course of researching a more efficient auricular acupuncture system for the rapid relief of pain. The name “Battlefield Acupuncture” was coined by Richard Niemtzow with the assumption that this novel system could be used on the military battlefield to deliver significant attenuation of pain in just a few minutes. While the exact mechanism of Battlefield acupuncture for pain relief is unknown, it likely alters the processing and the modulation of pain in the Central Nervous System involving the hypothalamus, thalamus, cingulate gyrus and cerebral cortex structures. BFA includes 5 auricular acupuncture points placed in the following sequence: cingulate gyrus, thalamus, Omega 2, Point Zero and Shen Men. Instead of using Omega 2, which is for extremity pain, the Gold protocol substitutes a point that corresponds to the cervix on the left ear and a point that corresponds to the uterus on the right ear (Olesen, Auriculotherapy Manual 1996, page 105). The rest of the original BFA points are included in the Gold protocol because they influence pain perception. After proper hand washing, the auriculotherapist wil clean each of the 5 sites with alcohol, and will place the beads, needles or placebo patches on the designated sites. **Follow-up procedure:** Participants will receive text messages at 8pm for the next four days to assess pain and anxiety (during the previous 24 hours). These assessments will use the same VAS instruments as at baseline. At the one-week follow-up visit, the participant will complete the

same VAS-P and VAS-A scales as at baseline and during the week. The research assistant will remove the patches at the follow-up visit. Criteria for subject discontinuation: Participants may withdraw from the study at any point.

Informed Consent Process: We will recruit participants at CUIMC clinics that provide medication abortion VC10 and at 1790 Broadway in New York City, NY. CUIMC serves a largely Latin population in the Washington Heights neighborhood of Manhattan that is English and Spanish speaking, both privately or publicly insured. Up to 20 patients per week are scheduled for medication abortion visits. From the previous acupuncture study in our division, we expect to recruit at least 5 participants weekly for a total of 150 patients, and 50 patients per treatment arm over 30 weeks (Ndubisi, 2018).

After completing all routine clinical care, the clinician will offer interested patients the opportunity to enter the study. The research assistant will determine patients eligibility and discuss the study with each woman. If a patient states interest in the study and meets inclusion criteria, the research assistant will proceed with the informed consent process; the informed consent process will begin with a concise and focused presentation of the key information about the study; potential subjects will have an opportunity to discuss the information provided; the informed consent process as a whole will present information in sufficient detail; this process will culminate with signing the required HIPAA and Columbia University consent forms. The consent form (and all study documents) will also have the option to use a paper-based consent process and to receive a copy of the consent either on paper or by email. The electronic version will contain all of the required elements. The research assistant will read and discuss all elements of the informed consent in person with the participant, and will assist in navigating the electronic device. The participant will not at any time have to go through the informed consent alone; the research assistant will always be present to read, to explain, to assess understanding, and to answer the participant's questions. Participants will provide a signature directly on the tablet screen, or if preferred on a paper version of the consent form. The date and time of the consent will be automatically recorded in Redcap. Redcap will provide secure storage and archiving of all consent forms. Note that this study will only recruit registered patients, and at the time of registration, per clinic routine, patients must provide proof of identity with a government-issued identification. All recruits to this study will be pregnant women who are registered at the clinic in order to obtain medication abortion with mifepristone and misoprostol. Recruitment will take place AFTER clinical activities are complete and after the patient has signed consent for her clinical care. The study consent form specifies that this is a trial of pain relief for women seeking abortion. Once a subject signs the consent form, she will proceed to be randomized and receive study treatment the same day.

Research Question(s)/Hypothesis(es)

The goal of this study is to test the hypothesis that auriculotherapy (with beads or needles), in addition to usual care with ibuprofen will minimize pain during medication abortion.

Primary Objective: To assess whether usual care plus auricular acupressure with beads or auricular acupuncture with needles reduces subject-reported maximum pain during medication abortion compared to usual care plus placebo.

Hypothesis: The median subject-reported maximum pain score, measured using a 100 mm VAS, among women receiving usual care plus either type of auriculotherapy, will be at least 20 mm less than the women receiving usual care plus placebo patches.

Secondary Objective: To assess whether usual care plus either auriculotherapy reduces subject-reported anxiety scores during medication abortion compared to women receiving usual care plus placebo.

Hypothesis: The median subject-reported maximum anxiety score, measured using a 100mm VAS, among women receiving usual care plus either type of auriculotherapy, will be at least 15 mm less than the women receiving usual care plus placebo patches.

Exploratory Objective: To compare pain scores during medication abortion with usual care plus auricular acupuncture with Pyonex needles vs pain scores with usual care plus auricular acupressure with beads.

Null Hypothesis: The median subject-reported maximum pain score, measured using a 100mm VAS, among women receiving auricular acupressure will not be different from pain score among women receiving auricular acupuncture.

Scientific Abstract

In the U.S., over 100,000 abortions per annum are medication abortions initiated before 10 weeks gestation with nonsteroidal anti-inflammatory drugs as the only analgesics. Pain control is often inadequate with the majority of patients reporting moderate or severe pain. Auricular acupuncture and acupressure may be a safe, low-cost, effective alternative to using NSAIDs alone or to using opioid analgesics. A prior randomized controlled trial completed in our department revealed substantially lower pain and anxiety scores among women assigned to auricular acupuncture compared to women assigned to placebo with usual care or usual care alone during first-trimester vacuum aspiration. Notwithstanding these promising results, acupuncture with needles is highly regulated in most states, and therefore its availability may be limited. Acupressure is not regulated to the same extent as acupuncture as it is non-invasive and without skin penetration and thus may be a more easily implemented treatment. Therefore, we propose a three-arm trial to assess maximum pain and anxiety scores, measured with a 100mm VAS, during medication abortion with participants randomized to either (1) auricular acupressure with Accu-patch beads plus usual care, (2) auricular acupuncture with Pyonex™ needles plus usual care, or (3) placebo patches plus usual care. The goal of this study is to test the hypothesis that auriculotherapy plus ibuprofen will be associated with less pain than ibuprofen alone during first trimester medication abortion.

Devices

Device name: Seirin Pyonex Singles

Device description: Single-use 1.2mm acupuncture press needles

Device Model/Version #: Pyonex singles

Manufacturer Information: Seirin-America, Inc.

Device name: Accu-patch Pellets (Beads)

Device description: Single-use gold-plated 1.2mm beads
Device Model/Version #: LH.ACUP.G.CLR
Manufacturer Information: Lhasa Oms, Inc.

Data Safety & Monitoring

The study PI and sub-investigators with medical expertise will monitor the study. In addition to routine medical expertise, all investigators will have received additional training in auriculotherapy from Dr. Melanie Gold, who is board-certified in medical acupuncture and who is co-PI of the project. The study coordinator will review and record possible adverse events with each participant at the one-week study exit visit, and an investigator will review all of these. During the course of the study, the PI will report in an expedited manner all Suspected Unexpected Serious Adverse reactions in accordance to FDA, HHS and IRB guidelines

Adverse events (AE): The investigators (or designated coordinator) will record all adverse events regardless of seriousness or relationship to the study intervention occurring from the signature of the informed consent to the last visit planned (one week later). The investigator will specify the onset date, the severity grade (Mild, Moderate or Severe), actions taken with respect to the study intervention, corrective treatment given, additional investigations performed, outcome and will give an opinion as to whether there is a reasonable possibility that the adverse event was caused by the study intervention. The Investigator will report all serious adverse events to the IRB within 24 hours of discovery if the investigator determines that an adverse event meets the SAE definition. This study is investigating a new indication for using auriculotherapy (with medication abortion care), but auriculotherapy is a widely used pain management technique in other medical settings, and is considered to be extremely safe.

Data and Safety Monitoring: To ensure subject safety, the Quality Assurance Monitor for the Department of Obstetrics and Gynecology will carry out monitoring for this study. At each scheduled monitoring visit, the QA Monitor will randomly select a representative number of study subject charts and will perform a data query and review source records. Upon completion, the QA Monitor will submit a report of the findings to Dr. Westhoff (Principal Investigator), the research manager, the study coordinator, Dr. Ronald Wapner (Vice Chair of Research/Innovation) and Michelle DiVito RN, MSN (Senior Director of Research Administration), with corrective actions if necessary. The Principal Investigator will also be responsible for monitoring the trial, starting at the point the patient begins the study. The medical members of the research team will make the determination of relationship of each adverse effect to the study intervention (auriculotherapy). During the study, the Principal Investigator or study site personnel will be responsible for querying and recording adverse events and serious adverse events.

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