Sphenopalatine Ganglion Block for PostDural Puncture Headache in Obstetric Postpartum Patients

Protocol: 16-1596
NCT: 02962427
Date: 10/26/2016

Protocol Synopsis Sheet

Below is the format to follow for the concept sheet for protocols. The point of a synopsis is that the critical elements of the protocol are summarized in a succinct manner. Bulleted or numbered lists should be used wherever possible.

lease limit your protocol concept sheet synopsis to four-to-five (4 - 5) pages (using 11-Ppoint Arial or 12-point Times New Roman typeface with one-inch margins). Please include your biosketch in the NIH format.

SYNOPSIS

Title of Study: Sphenopalatine Ganglion Block for PostDural Puncture Headache in Obstetric Postpartum Patients
Sponsor: None
Investigators: Dr. Cristina Wood MD MS, Dr. Rachel Kacmar MD, Dr. Rachael Rzasa-Lynn MD PhD
Research Mentor: None
Study Center(s): University of Colorado Hospital
Clinical Phase (I, II, III)
Hypothesis: Sphenopalatine Ganglion Block is as effective as epidural blood patch for relieving post-dural puncture headache pain in postpartum obstetric patients
Aims: Specific Primary Aim: Compare the effectiveness of a sphenopalatine ganglion block to an epidural blood patch for postdural puncture headache relief in randomized postpartum parturients over a 48 period. Specific Secondary Aim: Compare the effectiveness of a sphenopalatine ganglion block in known versus unknown dural puncture for postdural puncture headache relief in randomized postpartum parturients over a 48 period.
Primary Objective(s): Compare pain scores after sphenopalatine ganglion block or epidural blood patch for postdural puncture headache treatment in postpartum parturients.
Secondary Objective(s): Evaluate effectiveness of sphenopalatine ganglion block and epidural blood patch for known and unknown dural puncture in postpartum parturients with PDPH.
Exploratory Objective (s): To determine if a minimally invasive technique (sphenopalatine ganglion block) is as effective in treating post-dural puncture headache in postpartum parturients as an invasive technique (epidural blood patch)
Study Design/Methods: After approval by the Institutional Review Board and completion of informed patient consent, we will include obstetric postpartum parturients presenting with a diagnosis of post-dural puncture headache (PDPH) as defined by the International Classification of Headache Disorders. These are both procedures utilized for the treatment of post-dural puncture headaches on the labor and delivery floor currently. Each study participant will be randomized to receive either an EBP or a SPGB; however, if the SPGB or EBP fails initially or subsequent failure within the 48 hour time period, the participant will be offered another SPGB or an EBP if in the SPGB arm or simply another EBP if in the EBP arm.

Maximum of 2 SPGB or EBP per patient.
We will also collect patient age, gravity, parity, BMI, ASA status, history of any headaches including migraines during or prior to pregnancy, details and timing of the original neuraxial procedure, delivery mode and details and other interventions attempted to relieve the headache (including repeated SPGB or EBP within 48 hours). We will document resolution of headache at 1 hour, 24 hours and 48 hours after procedure utilizing NRS scores (1-10). All documentation will be stored and accessed in our electronic medical record (Epic®).

Study Period: 7/1/2016 – 7/1/2019

Study Population: Postpartum obstetric parturients diagnosed with a post-dural puncture headache.

Number of Patients: 100 patients over a three year period

Timeline:
5/1/2016: Submission of IRB protocol
7/1/2016: IRB approval and beginning of enrollment of study subjects
7/1/2019: Completion of study
7/1/2019-9/1/2019: Completion of publication for submission

Main Criteria for Inclusion/Exclusion:
Inclusion Criteria:

1) Age 18 years or age or greater postpartum obstetric parturient
2) Diagnosis of post-dural puncture headache based on the International Classification of Headache Disorders:
    a. Any headache fulfilling criterion c
    b. Dural puncture has been performed
    c. Headache has developed within 5 days of the dural puncture
    d. Not better accounted for by another ICHD-3 diagnosis.
    e. Occurring immediately or within seconds of assuming an upright position and resolving quickly (within 1 minute) after lying horizontally.

Exclusion criteria:

1) Refusal to participate in the study
2) Non-english speaking
3) Placement of an EBP within the past 5 days
4) Allergy and/or intolerance to any the study materials
5) Contraindications to an EBP
6) Plan for therapeutic anticoagulation post-partum
7) Intolerance of at least 15mL of autologous blood via epidural or intolerance of the placement of the nasal swabs for 30 minutes
8) EBP less than 24 hour from neuraxial procedure/dural puncture

Data and Safety Monitoring Plan: The Principal Investigator (PI) will be responsible for the conduct of this study, including the blood sample handling and use, overseeing participant safety, executing the DSM plan, and complying with all reporting requirements to local and federal authorities. This oversight will be accomplished through additional oversight from the Data and Safety Monitoring Committee (DSMC) at the University of Colorado. The DSMC is responsible for ensuring data quality and patient safety for all clinical studies at the University of Colorado. A summary of the DSMC's activities is as follows:

- Conduct of internal audits
- Ongoing review of all serious adverse events (SAEs), unanticipated problems (UAPs) and reportable adverse events (AEs)
- Supervises internal DSM boards and/or performs as an internal DSMB (if requested)
- Has the authority to close and/or suspend studies for safety or conduct issues
- May submit recommendations for corrective actions to the Executive Committee

Per the DSM Plan, SAEs, UAPs and reportable AEs are reported to the DSMC, IRB and the sponsor per study protocol. All SAEs, UAPs and reportable AEs are to be reported to the DSMC within 5 business days of receiving notification of the occurrence.
Audits will consist of a review of the regulatory documents, consent forms, and source data verification. Results and recommendations from audits will then need to be submitted by the PI to the IRB of record at the time of the continuing review.

Risks to Patients: These are both procedures utilized for the treatment of post-dural puncture headaches on the labor and delivery floor currently.
Epidural blood patch: Common side effects include tenderness at site of injection and pressure in the lumbar spine. Rare risks include bleeding, infection, nerve damage, paralysis, dural puncture, no relief of symptoms.
Sphenopalatine ganglion block: Common risk is failure to relieve symptoms. Rare risks are damage to intranasal tissue or structures, anosmia or allergic reaction to medication.

Statistical Methods: There is a paucity of data in the literature evaluating the effect of EBP and SNB on PDPH pain using a numerical rating scale (NRS) or a visual analog scale (VAS). Most studies report outcomes in terms of complete, partial, or no relief. One study in 108 emergency department patients found that the correlation between a 10-point NRS scale and a VAS was 0.94 (95% CI 0.93-0.95), indicating that a verbally administered NRS can be substituted for the VAS in acute pain management. From our review of the few studies reporting NRS or VAS data, the baseline NRS or VAS in patients with PDPH is about 8-9 with a standard deviation of $\pm$ 1.5, which might be reduced to about 3-4 $\pm$ 3 1-6 hours after treatment, and perhaps to 1-2 $\pm$ 1.5 24-48 hours after treatment. Assuming that we wish to detect a 1-2 unit difference in the NRS between the 2 treatment groups as being clinically meaningful, we calculate that we will need to randomize about n = 100 patients (50 patients in each treatment group) to achieve a statistical power of 90% for the trial.

The study data will be entered into REDCAP. Frequency distributions will be calculated for all variables to determine if the distributions of values look reasonable and if there are any outliers in the data. Suspected outliers will be corrected if needed, or truncated, or recoded as missing. Distributions will be tested for a normal (Gaussian) distribution. The primary statistical analysis will be by intention-to-treat. Treatment groups will be compared on demographic and clinical characteristics at baseline (Table 1). A CONSORT diagram will be prepared to describe screening and entry of patients into the clinical trial, and disposition of all patients after randomization. NRS means and standard deviations will be calculated for each treatment group at baseline, and 1, 24, and 48 hours after treatment. These mean values between the 2 treatment groups over time will be tested for statistical significance using a longitudinal mixed linear model. Side effects, adverse effects, and serious adverse effects will be recorded and compared for

each treatment group. Publication of results will follow the CONSORT 2010 checklist.
Funding/Budget: Funding for the statistical analysis will be requested from the Department of Anesthesiology. All treatments and supplies are currently employed on the labor and delivery deck, no additional funding is needed.
Requested Departmental Support: Funding for the statistical analysis will be requested from the Department of Anesthesiology. All treatments and supplies are currently employed on the labor and delivery deck, no additional funding is needed.
Expected Outcomes: After completion of this study, we will be able to determine the effectiveness of SPGB for the treatment of PDPH when compared to EBP placement. If SPGB are effective, this could change the management and algorithm in the treatment of PDPH for postpartum parturients.

Please include your biosketch in the NIH format (follow link below)

http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&ved=0CDoQFjAC&url=http%3A%2F%2Fgrants.nih.gov%2Fgrants%2Ffunding%2Fphs398%2Fbiosketchsample.doc&ei=wMbxUo-hD8b4yAHd-4GADw&usg=AFQjCNE4b9iv7E-afLxtF7fDYQvH9U-Pcg&bvm=bv.60799247,d.aWc&cad=rja