PROMIS STUDY DESIGN AND DETAILED PROTOCOL

Study Title: PROtecting Maternal brains from Injury and Stroke (PROMIS)

NCT05726279

Last Date Used: 2/28/2025

Design

PROMIS (PROtecting Maternal brains from Injury and Stroke) was a Phase II, prospective, non-blinded, non-randomized, pilot clinical trial of cerebral hemodynamic monitoring in participants admitted to the hospital for treatment of preeclampsia with severe features in the postpartum period (within 6 weeks of delivery).

Participants were recruited in the first 24 hours of presentation of preeclampsia with select severe features (**Supplemental Table 1**) and placed into one of two consecutive study arms: an initial observational arm (monitoring cerebral autoregulation only; N=25) and a subsequent interventional arm (autoregulation-guided blood pressure management; N=25). The duration of the study intervention was 24 hours. Other interventions for preeclampsia, such as administration of high-dose magnesium sulfate, were not changed from standard of care treatment.

For the observational arm, the first patient was enrolled on 4 May 2023 and the observational arm was completed 7 March 2024. The interventional arm enrolled the first patient on 6 January 2025. The trial was stopped early on 28 February 2025 due to slow recruitment and end of the funding period.

Aims

The primary purpose of this study was to demonstrate the feasibility and safety of incorporating non-invasive bedside neuromonitoring approaches into clinical care of postpartum preeclampsia patients. These include monitoring the brain tissue oxygenation index (TOI), as a proxy for cerebral blood flow (CBF), using near-infrared spectroscopy (NIRS) and arterial blood pressure (ABP) using finger plethysmography.

Aim 1: Observational Arm

Calculate personalized limits of cerebral autoregulation in 25 patients with postpartum preeclampsia, using continuous monitoring of ABP and CBF.

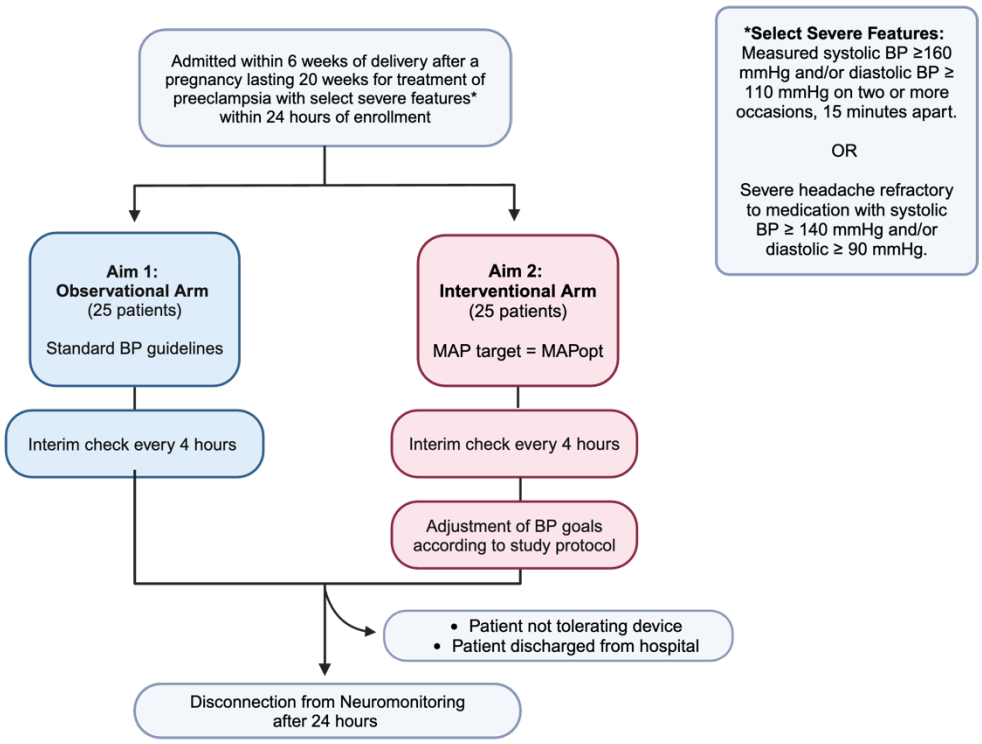
- Hypothesis 1: Over 24 hours of standard clinical care, guideline-based BP management will result in ≥10% of time during which MAP exceeds personalized upper or lower limits of autoregulation, calculated using an established threshold for autoregulatory dysfunction.

Aim 2: Interventional Arm

Pilot the use of autoregulation-guided BP goals in 25 patients with postpartum preeclampsia.

- Hypothesis 2: Targeted BP management using autoregulation-guided goals will result in less time spent outside limits of autoregulation, compared with Aim 1 patients managed according to current guidelines.
    - Hypothesis 2a: It is feasible and safe to implement autoregulation-guided blood pressure management in this patient population.
    - Hypothesis 2b: An exploratory effect size of autoregulation-guided blood pressure management on physiologic measures can be determined.

Flowchart of overall study procedure for both arms found in **Supplemental Figure 1**



Supplemental Figure 1: Flowchart of inclusion, treatment arm assignment, and study procedures in the PROMIS trial. BP= blood pressure; mmHg= millimeters of mercury

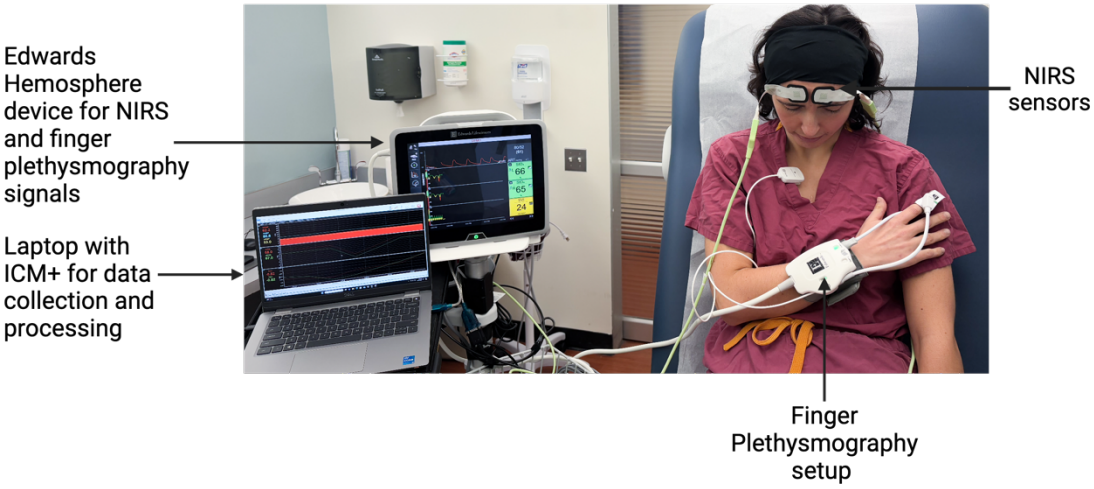
Methods and Measurements

Data Collection and Online Processing

In this study, the TOI was measured using NIRS probes (Foresight-Elite, Edwards Life Sciences, Irvine, CA) and ABP was measured using finger plethysmography (ClearSight or Acumen IQ cuff, Edwards Life Sciences, Irvine, CA) (**Supplemental Image 1**). This study used the Edwards Hemosphere device, an FDA-approved device, to collect the real-time hemodynamic and cerebral oxygenation data. Both CBF and ABP data was sampled at a frequency of 0.5 Hz and all data was processed and analyzed using ICM+ neuromonitoring software (https://icmplus.neurosurg.cam.ac.uk/) at bedside. The study also utilizes a portable sphygmomanometer device (WatchBP Home, Microlife U.S.A., Inc, Clearwater, Florida) to measure baseline blood pressure and heart rate.

Limits of Cerebral Autoregulation Algorithm

Refer to the methods section of *Continuous Blood Pressure and Cerebral Blood Flow Monitoring in Postpartum Preeclampsia with Severe Features* (Woolcock Martinez et al.) for details on computing individualized limits of cerebral autoregulation and optimal MAP (MAPopt).



Supplemental Figure 2: Neuromonitoring Setup. The monitoring setup required a device, such as the Edwards Hemosphere device seen here, to collect the ABP and TOI, and a laptop with ICM+ neuromonitoring software installed to sample the data. The adhesive NIRS probes (Foresight-Elite, Edwards Life Sciences, Irvine, CA) were placed on the frontal scalp, above the brow bones. The non-invasive finger plethysmography (ClearSight or Acumen IQ cuff, Edwards Life Sciences, Irvine, CA) was placed on the first three digits of either hand between the distal interphalangeal joint and the proximal interphalangeal joint and was connected to the wrist cuff seen in the image. ICM+ would compute the tissue oxygenation index (TOx) in real time and displayed the values on the laptop. ICM+ was also capable of computing the limits of autoregulation from the NIRS and ABP data. All devices used were FDA approved.

Assessment of Compliance

Compliance with the protocol was assessed every four hours at bedside neuromonitoring checks performed by study personnel and the clinical team. This interval was selected to coincide with the timing of standard nursing checks and vital sign measurements in the postpartum setting. A standardized checklist was used for both study arms at each interim check to promote compliance to the neuromonitoring protocol. An ICM+ module was utilized in the interventional arm to maintain compliance with autoregulation-guided blood pressure management. The treating clinician could deviate from autoregulation-guided

recommendations but was required to provide commentary in the modules. The checklist and ICM+ module are both detailed in the protocol sections below.

Outcome Measures

Primary Outcome

The primary objective of this study was to assess the feasibility of non-invasively measuring cerebral hemodynamics to calculate autoregulation-guided blood pressure targets in patients with postpartum preeclampsia. Aim 1 was an observational cohort study of 25 patients treated according to standard of practice with fixed BP targets. In Aim 2, we compared patients treated with autoregulation-guided BP targets to the observational cohort. For the primary analysis, we measured (in hours) the total time each patient had MAP values within their computed limits of autoregulation. The primary outcome was the percentage of time during which MAP was within limits of autoregulation during the 24 hours after initiation of monitoring (i.e., time within target range).

Secondary Outcome: Safety

Secondary outcomes included presence or absence of neurological symptoms, defined as ≥8/10 headache pain, or blurred vision, assessed every four hours during the monitoring period by study personnel at the time of clinical vital sign checks.

Safety outcomes included any new acute neurological deterioration, defined as decreased level of consciousness (Glasgow Coma Scale of 12 or less, indicating moderate to severe brain injury), new focal neurological deficits, or seizure.

Exploratory Outcome: Efficacy/Effect Size

The exploratory outcomes of this study included efficacy and effect size of autoregulation-guided blood pressure management in increasing time spent within limits of cerebral autoregulation.

Study Population

Eligibility criteria are delineated in **Supplemental Table 1** and were the same for both arms of the study. Eligible participants admitted to the obstetrics unit were identified by clinical providers and/or the research team throughout their admission for care. Patients who had given birth within the previous 6 weeks after a pregnancy lasting at least 20 weeks and were admitted to any inpatient obstetrics unit within 24 hours for active management of hypertension were screened for the study and, if eligible, approached and consented in accordance with the IRB-approved protocol.

Supplement Table 1: PROMIS Study Inclusion and Exclusion Criteria	
Inclusion Criteria	▪ Admitted to the CUIMC within 6 weeks of delivery after a pregnancy lasting 20 weeks. ▪ Admitted for treatment of preeclampsia with selected severe features within 24 hours of enrollment, defined as either: ☐ measured systolic BP ≥160 mmHg and/or diastolic BP ≥ 110 mmHg on two or more occasions, 15 minutes apart. ☐ severe headache refractory to medication with systolic BP ≥ 140 mmHg and/or diastolic ≥ 90 mmHg. ▪ If no severe features within 24 hours of enrollment: received IV magnesium within 12 hours of enrollment for treatment of selected features as indicated above
Exclusion Criteria	History of any of the following: ▪ Acute ischemic stroke ▪ Intracerebral hemorrhage ▪ Subarachnoid hemorrhage ▪ Eclamptic seizures ▪ Raynaud's syndrome ▪ Any other neurological complication requiring transfer to the neurological intensive care unit or stroke step down unit. Inability to understand and consent to the study

Study Arms

This is a non-randomized, non-blinded trial. The first 25 participants enrolled in PROMIS were placed in the observational arm; the second 25 were placed in the interventional arm.

Aim 1 Observational Study Protocol

The study was executed according to **Supplemental Figure 2**. After the team enrolled participants and obtained written informed consent, subjects were connected to the neuromonitoring setup. The team recorded the time at which the participant was connected to the neuromonitoring setup. Baseline blood pressure and heart rate were measured by the study sphygmomanometer device. Blood pressure reading from the finger plethysmography device was also recorded. Baseline symptoms and Glasgow coma scale rating were recorded. All medications dosed within the past 24 hours were documented, including medication name, dosing amount, and frequency. Participants receiving high-dose intravenous magnesium sulfate had their bolus dose, infusion rate, and start/stop times recorded. Participants complete a migraine questionnaire as shown in **Supplemental Figure 3.**

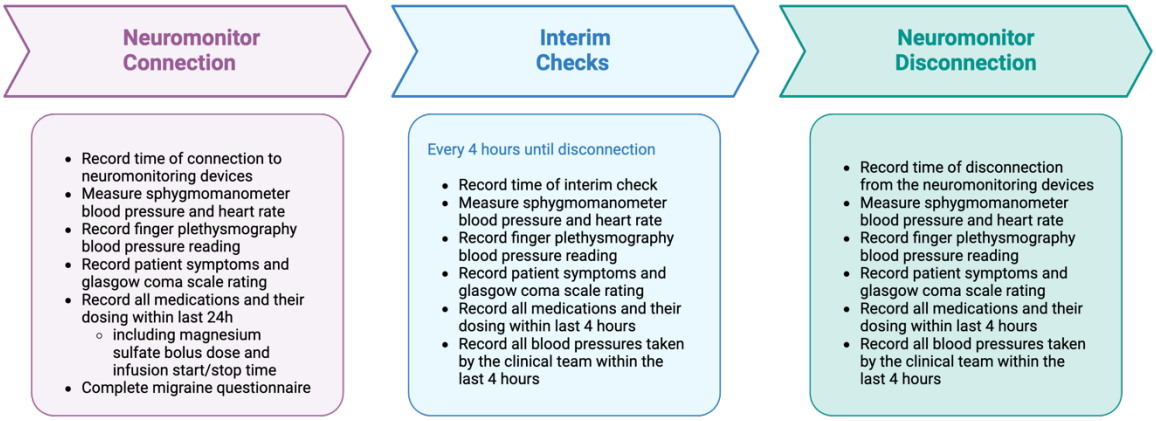
After monitoring was initiated, study personnel performed bedside checks every four hours. During these bedside checks, personnel ensured that data was still properly being collected and that the participant was tolerating the device. Interim checks also include recording the following data:

1. Time of the interim check
2. Heart rate, systolic blood pressure and diastolic blood pressure measured with the study sphygmomanometer
3. Systolic and diastolic blood pressure seen on the neuromonitoring Hemosphere screen (and measured by the study finger plethysmography)
4. If a neurologist had been consulted or brain imaging had been obtained (y/n) within the past 4 hours
5. Patient symptoms at time of check
    a. If patient endorsed a headache: headache pain level at time of check
6. Medications (including dosing and frequency) administered in the previous 4 hours, including but not limited to magnesium sulfate, anti-hypertensives, analgesics, and anti-emetics.
    a. If received magnesium: start/stop times of infusions
    b. Most recent magnesium serum level was documented, including the date/time the specimen was collected
7. Glasgow coma scale
8. All blood pressure readings taken by the clinical team within the past 4 hours

Data was entered into REDCap at the 4, 8, 12, 16, 20, and 24-hour marks.

Participants were disconnected from the neuromonitor if they completed 24 hours of monitoring, if they no longer tolerated the study, or if they were discharged from the hospital. The time of disconnection from the Hemosphere was recorded. Blood pressure

and heart rate readings were taken with the study sphygmomanometer at time of disconnection. The finger plethysmography blood pressure readings shown on the Hemosphere device was also recorded. Glasgow coma scale, all symptoms, all medications administered (including dosing and frequency) since the last interim check, and all blood pressure readings made by the clinical team since the last interim check were recorded.



Supplemental Figure 3: Observational Arm Additional Data Collection Flow Diagram. Study monitoring began once the participant was connected to the neuromonitoring devices and continued for 24 hours or until the participant was discharged from the postpartum floor, whichever came first. The study personnel would perform an intermittent beside check every 4 hours at which point they would ensure the data was being collected properly, the participant was tolerating the device, and they would collect certain study and clinical variables

Aim 2 Interventional Arm Study Protocol

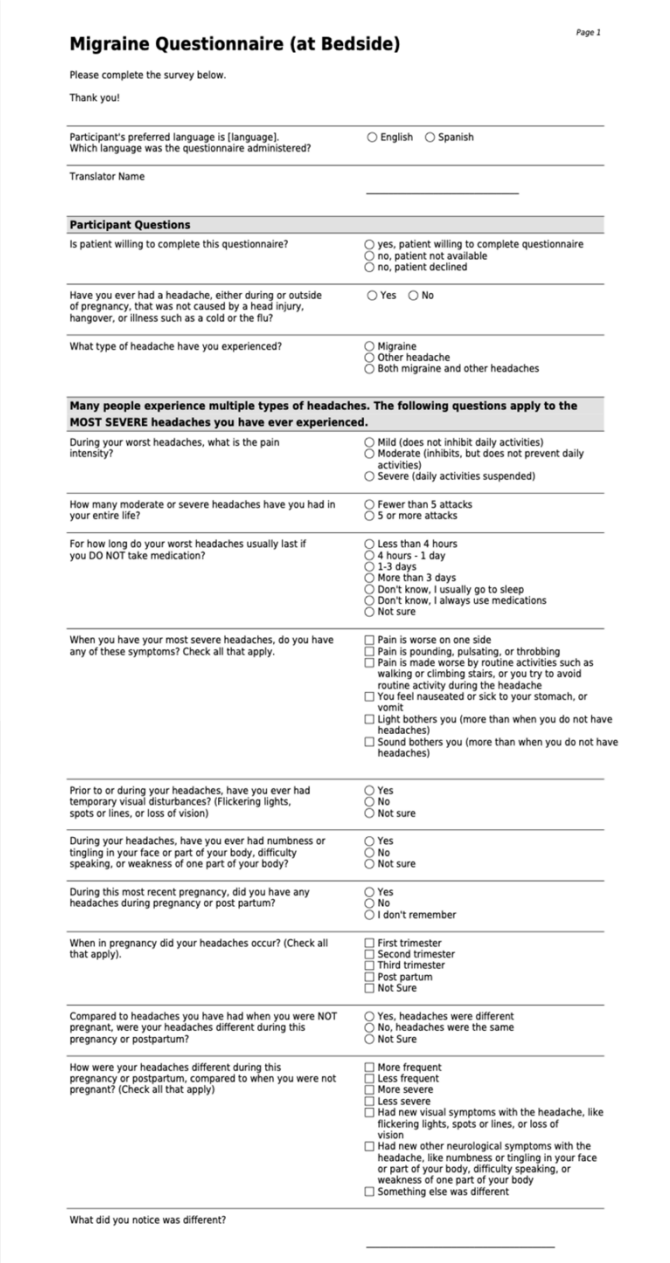
Participants in the interventional arm were connected to the neuromonitoring device, underwent interim checks every four hours, and were disconnected in the same fashion as those in the observational arm are as described above (**Supplemental Figure 2**). However, participants enrolled in the interventional arm underwent an interim check (as seen in the observational arm) *and* MAP protocol overview at the following predetermined 4-hour intervals: 6:00, 10:00, 14:00, 18:00, 22:00, 2:00. At this time, study personnel presented to the participant's bedside with the provider working on the study to complete an ICM+ module customized for the study (**Supplemental Figure 5**). Current MAP value and MAPopt target value were displayed. Study personnel reviewed a series of questions

prompted by ICM+ with the provider, making selections based on provider feedback, shown below (**Supplemental Figure 6)**:

- Q1: Were there any problems adopting the last blood pressure target?
    - A: Options provided in the drop-down menu: "Yes" or "No"
- Q1a (if "Yes" to Q1): What was the problem with adopting the previous target?
    - A: Options provided in the drop-down menu:
        - "The recommended target was too high"
        - "The recommended target was too low"
        - "Other"
- Q1b (if "Other" to Q1a): Please specify
    - A: [Free text option]
- Q2: Will you be adopting the advised blood pressure target?
    - A: Options provided in the drop-down menu: "Yes" or "No"
- Q3a (if "No" to Q2): What is the reason for not adopting the advised MAP target?
    - A: Options provided in the drop-down menu:
        - "The advised target is too high"
        - "The advised target is too low"
        - "The intervention to reach the advised target may harm the patient"
        - "Other"
- Q3b (if "Other" to Q3a): Please specify
    - A: [Free text option]
- Q4 (if "No" to Q2): What MAP will you be targeting?
    - A: [Data field for MAP entry]
- Q5a: What intervention are you planning to achieve the target?
    - A: Options provided in the drop-down menu:
        - "None needed"
        - "Increase BP with IV fluids bolus"
        - "Increase BP with vasopressors"
        - "Lower BP"
        - "Other"
- Q5b (if "Other" to Q5a): Please specify.
    - A: [Free text option]
- Q6: Any comments?
    - A: [Free text option]

After reviewing the above questions with the provider, study personnel entered a pending order through the electronic medical record reflecting changes to the blood pressure regimen, aimed at guiding current MAP to MAPopt, for approval by the provider. All clinical

decisions were made in the context of the overall clinical management and in collaboration with the maternal-fetal medicine team caring for the participant during admission.



Page 1

Migraine Questionnaire (at Bedside)

Please complete the survey below.

Thank you!

Participant's preferred language is [language]. Which language was the questionnaire administered?	○ English ○ Spanish
Translator Name	_____

Participant Questions

Is patient willing to complete this questionnaire?	○ yes, patient willing to complete questionnaire ○ no, patient not available ○ no, patient declined
Have you ever had a headache, either during or outside of pregnancy, that was not caused by a head injury, hangover, or illness such as a cold or the flu?	○ Yes ○ No
What type of headache have you experienced?	○ Migraine ○ Other headache ○ Both migraine and other headaches

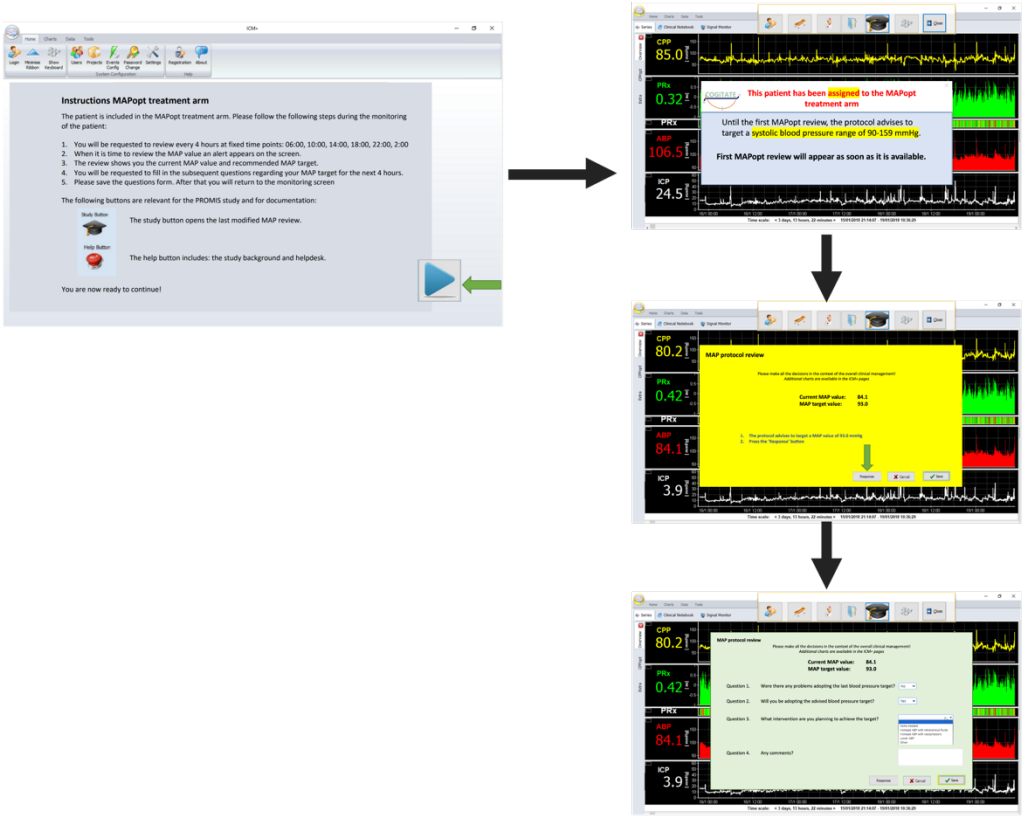
Many people experience multiple types of headaches. The following questions apply to the MOST SEVERE headaches you have ever experienced.

During your worst headaches, what is the pain intensity?	○ Mild (does not inhibit daily activities) ○ Moderate (inhibits, but does not prevent daily activities) ○ Severe (daily activities suspended)
How many moderate or severe headaches have you had in your entire life?	○ Fewer than 5 attacks ○ 5 or more attacks
For how long do your worst headaches usually last if you DO NOT take medication?	○ Less than 4 hours ○ 4 hours - 1 day ○ 1-3 days ○ More than 3 days ○ Don't know, I usually go to sleep ○ Don't know, I always use medications ○ Not sure
When you have your most severe headaches, do you have any of these symptoms? Check all that apply.	☐ Pain is worse on one side ☐ Pain is pounding, pulsating, or throbbing ☐ Pain is made worse by routine activities such as walking or climbing stairs, or you try to avoid routine activity during the headache ☐ You feel nauseated or sick to your stomach, or vomit ☐ Light bothers you (more than when you do not have headaches) ☐ Sound bothers you (more than when you do not have headaches)
Prior to or during your headaches, have you ever had temporary visual disturbances? (Flickering lights, spots or lines, or loss of vision)	○ Yes ○ No ○ Not sure
During your headaches, have you ever had numbness or tingling in your face or part of your body, difficulty speaking, or weakness of one part of your body?	○ Yes ○ No ○ Not sure
During this most recent pregnancy, did you have any headaches during pregnancy or post partum?	○ Yes ○ No ○ I don't remember
When in pregnancy did your headaches occur? (Check all that apply).	☐ First trimester ☐ Second trimester ☐ Third trimester ☐ Post partum ☐ Not Sure
Compared to headaches you have had when you were NOT pregnant, were your headaches different during this pregnancy or postpartum?	○ Yes, headaches were different ○ No, headaches were the same ○ Not Sure
How were your headaches different during this pregnancy or postpartum, compared to when you were not pregnant? (Check all that apply)	☐ More frequent ☐ Less frequent ☐ More severe ☐ Less severe ☐ Had new visual symptoms with the headache, like flickering lights, spots or lines, or loss of vision ☐ Had new other neurological symptoms with the headache, like numbness or tingling in your face or part of your body, difficulty speaking, or weakness of one part of your body ☐ Something else was different
What did you notice was different?	_____

Supplemental Figure 4: Migraine Questionnaire

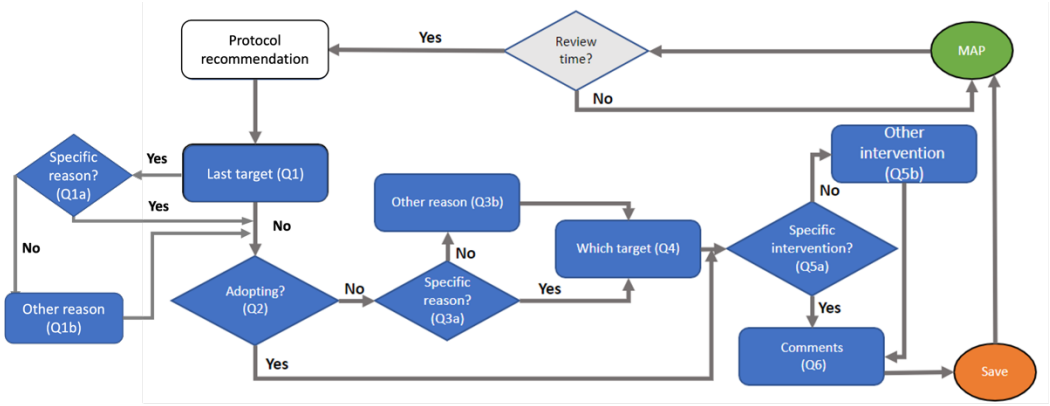
Participants were provided with a questionnaire to elicit their history of headaches, including headaches during pregnancy, when connected to the neuromonitoring device. The forms were provided to participants at the time of connection to the neuromonitor,

with officially translated versions made available for those whose primary language was Spanish.



Supplemental Figure 5: Example Interventional Arm Treatment to MAPopt Workflow

Study personnel and clinical team completed an ICM+ module at pre-specified timepoints. The module displayed the current MAP and the MAPopt based on the participant's autoregulatory function. The team completed the questionnaire to determine changes to blood pressure management that maintain MAPopt.



Supplemental Figure 6: Master Flowchart for Review Questions Prompted by ICM+ Module

Sample Size

The sample size was calculated to power the study to detect a difference in time spent outside personalized limits of autoregulation between the interventional and observational arms. All analyses were conducted according to an intention-to-treat principle. Thus, all patients enrolled (and consented) were included in the analysis regardless of their compliance with the protocol and the treatment schedule.

Data from stroke patients, another population with labile blood pressure, showed that patients spent on average 65.7% (± 22.9%) of their monitored time within their personalized limits of autoregulation (time within target range) (Petersen et al., Stroke 2020;51:914-921). Extrapolating from these data, with a total of 25 patients in the single interventional arm and a projected SD of 22.9%, we would have over 80% power to demonstrate an absolute increase of 15% in this metric compared to the observational cohort (a = 5%, two-sided t-test). Of note, one purpose of this trial was to determine an effect size for planning purposes for a larger randomized trial.

Data Storage

Data were managed in accordance with standard protocols and data protection laws aimed at ensuring that confidentiality is maintained at all times.

Participant data was assigned a numerical deidentification code. An enrollment log documented the link between study number and participant identity and was stored in a locked cabinet and secured computer database (on a password-protected network drive).

Continuous MAP and tissue oxygenation data were collected to calculate personalized limits of autoregulation. Data was transferred to secure local servers. Access to the

servers was limited to study personnel, who had completed and passed IRB and HIPAA training.

Subject biochemical and clinical data, collected as described in the study protocol, were maintained on a secure, encrypted, web-based online database, Research Electronic Data Capture (REDCap), also accessible only to study personnel. Raw data was identified only with the unique study identifier for each subject.

Statistical Plan

Baseline characteristics of included subjects were summarized by means and standard deviations (SD) for normally distributed continuous variables (as determined by the Shapiro-Wilks test), by medians and interquartile ranges (IQR) for skewed continuous variables, and by numbers (%) for categorical variables. For the analysis of continuous values, an independent sample t-test (or a Mann-Whitney U test where appropriate) was used. For the analysis of categorical variables, a Chi-squared test (or where appropriate Fisher's exact test) was used.

For the primary analysis, we computed the percentage of the 24-hour monitoring period during which MAP was within personalized limits of autoregulation. Time within target range, secondary outcomes, and safety outcomes of the interventional arm was compared to that of controls from our observational arm using appropriate statistical tests.

All data were analyzed on an intention-to-treat basis, regardless of compliance with the treatment protocol. All participants who enrolled and consented were included in the analysis.

Patient and Public Involvement

Patients or the public were not involved in the design, or conduct, or reporting or dissemination plans of our research.

Ethics and Dissemination

Informed Consent

The Institutional Review Board (IRB) approved this study prior to initiation of recruitment. Participants signed an informed consent form prior to enrollment following all established IRB guidelines. The consent form was written in language that a person with a 6th grade education could understand. At the time of recruitment, the research staff member gave a complete description of the study to the prospective participant in clear, easy-to-understand language. For those interested in participating, a copy of the consent form was

provided, and the research staff member reviewed the critical points and answered any questions. The staff member ensured that the person fully understood the details of the monitoring periods, including the duration and the frequency of all measurements. After answering any questions the participant had, if the person wished to participate, she signed the informed consent document, and the staff member co-signed it. The HIPAA Authorization for Research was also signed at this time.

Spanish-Speaking Subjects

This study served a large Spanish-speaking patient population. We developed strategies to accommodate this cultural diversity and minimize potential language barriers. The majority (approx. 90%) of our research staff was bilingual in Spanish and English. Hispanic/Latinx participants were provided with a copy of the consent form and HIPAA form in Spanish, depending on which language they were most comfortable speaking and reading. All verbal explanations and answers to ensuing questions were provided in the participants' preferred language. If bilingual staff were unavailable, non-Spanish speaking staff members utilized the professional phone interpreter services provided through the hospital.

Safety Considerations

Data and Safety Monitoring Plan

To monitor data and safety, we established an independent data safety monitoring board (DSMB) consisting of experts in their fields. Primary responsibilities included (i) periodic review and evaluation of the accumulated study data for participant safety, study conduct and progress; and (ii) to make recommendations to the project PI regarding the continuation, modification, or termination of the trial. Members convened by webinar once before the start of the trial and every 6 months thereafter. At the initial meeting, they reviewed and confirmed their acceptance of the protocols, established guidelines for review, defined a quorum, and drew guidelines for monitoring the study. Before each meeting, a formal detailed statistical report is provided, including the results of every aspect of the project: baseline variables, protocol adherence, adverse events reported and center performance in terms of recruitment, data quality, loss to follow-up and protocol deviations and violations.

The DSMB was available to receive reports of any spontaneously reported serious adverse events. They received continuously revised tabulations of three serious adverse events plausibly related to blood pressure changes, which investigators monitored and surveyed during the participation in the study: acute neurological deterioration, ischemic stroke,

and intracranial hemorrhage. The DSMB had the authority to request additional information and recommend cessation of treatment for any individual trial participant. If the DSMB observed a significant increase in serious adverse events in the intervention group, compared to historical controls and rates observed in subjects enrolled in Aim 1 of the study, the DSMB chair would meet with the research team and recommend appropriate action. Working with the DSMB, the research team (P.I., co-investigators, consultants) could suspend the study or revise the protocol. If the members of the DSMB and the study team could not agree on a course of action, the IRB would be informed immediately, and the P.I. would propose a resolution to be approved by the IRB. The same reports given to the DSMB would be reviewed by the P.I. who would be vigilant to increases in adverse events.

We did not anticipate any serious adverse events from minor blood pressure adjustments within the blood pressure range recommended by current guidelines; however, ischemic and/or hemorrhagic stroke were theoretically possible. These were monitored and reported as described above. The P.I. apprised the mentorship team and study personnel of all spontaneously reported and tabulated adverse events during regular study meetings and via email as they were reviewed. Serious, unanticipated and related adverse events would be reported in writing within 24 hours to the institutional board governing human research. The protocol's Independent Safety Monitors would be informed of moderate or greater in severity (see below) adverse events within 1 day of the event becoming known to the P.I. In addition, the board reviewed the safety data after every 5 enrollments.

Definition of Adverse Events:

Adverse events were monitored for each subject participating in the study. The primary investigator determined whether an adverse event was attributed to the study protocol and graded the severity of the adverse event. Only serious adverse events would be reported and followed beyond hospital discharge.

Safety Procedures

This study featured assessment of blood pressure and neurological symptoms, including headache, vision changes, and other neurological deficits. Because issues of patient safety were inherent in assessing blood pressure and neurological assessments, protocols were in place for research staff to follow, should a participant demonstrate concerning symptoms or signs. In addition, protocols were in place in case of obstetrical emergencies during the period of study monitoring.

In the interventional arm, to ensure that blood pressure management therapy did not present any safety risk to study subjects, we used specific safety-stopping rules. Given the

rarity of pregnancy associated stroke and the small sample of 25 participants in the observational or interventional arm, the safety-stopping rule mandated a cessation of enrollment if any stroke is observed that was at least probably related to the intervention.

Hypertensive emergency
To minimize risk of harm, we implemented the following strict safety protocols. Any measured BP of ≥160/110 triggered closer monitoring of the patient and re-assessment every 15 minutes by the clinical team. Sustained systolic BP ≥180 on two consecutive 15-minute checks, or any single systolic BP ≥220 or diastolic ≥120 mmHg triggered immediate "escape" from the trial protocol.

Neurological symptoms or signs
A brief neurological history was obtained by study personnel at the start of the study and throughout the monitoring period, including current neurological symptoms such as headache, vision changes, weakness, speech difficulty, numbness, or gait impairment. If a subject reported any of these symptoms, a board-certified or board-eligible neurologist would be notified immediately to perform a full neurological assessment and obtain further neurological testing as clinically warranted. Any acute change in neurological status triggered "escape" from the trial and immediate evaluation by the 24-hour in-house clinical stroke team, per standard hospital protocols.

The study site had 24-hour coverage by resident neurologists and neurocritical care and/or stroke fellows who were board-eligible or board-certified in neurology. In addition, the study personnel included a board-certified vascular neurologist available 24/7 as backup in case of neurological emergency.

Obstetrical emergencies
All clinical obstetrical care was managed by the participants' inpatient obstetrics team. If an obstetrical emergency occurred while undergoing the cerebral autoregulation study in the Obstetrics Postpartum unit, the primary obstetrician or obstetrics team would be immediately notified. A maternal-fetal medicine fellow and attending physician were in house at all times, 24 hours/day, 7 days/week.

Any adverse event would be reported immediately to the Institutional Review Board and any major adverse event would trigger an immediate convening of the DSMB to review the protocol and if indicated, stop the study.

Funding

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