THE UNIVERSITY OF ALABAMA AT BIRMINGHAM
Office of the Institutional Review Board for Human Use

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APPROVAL LETTER

TO: Ness, Timothy J

FROM: University of Alabama at Birmingham Institutional Review Board
Federalwide Assurance # FWA00005960
IORG Registration # IRB00000196 (IRB 01)
IORG Registration # IRB00000726 (IRB 02)
IORG Registration # IRB00012550 (IRB 03)

DATE: 21-Feb-2022

RE: IRB-300002466
IRB-300002466-015
Baclofen as a Perioperative Analgesic Adjuvant for Kidney Stone Surgery

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The IRB reviewed and approved the Continuing Review submitted on 11-Jan-2022 for the above referenced project. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services.

Type of Review: Full (Institutional Review Board 02 (UAB))
Determination: Approved
Approval Date: 16-Feb-2022
Approval Period: One Year
Expiration Date: 15-Feb-2023

ML/cyh

Documents Included in Review:

- response.220111
- CONTINUING REVIEW EFORM

– Last approval of protocol during recruitment
– Following pages are the 8/2/2019 consent form version which was re-approved in identical form annually.

Randomized Informed Consent And HIPAA Authorization

Record ID _____

INFORMED CONSENT FORM

TITLE OF RESEARCH: Baclofen as a Perioperative Analgesic Adjuvant for Kidney Stone Surgery (Randomized)

IRB PROTOCOL: IRB-300002466

INVESTIGATOR: Dr. Mark Mandabach

SPONSOR: UAB Department of Anesthesiology and Perioperative Medicine

[redacted]

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of this study is to evaluate how well a medication called Baclofen controls your pain after kidney stone surgery.
Duration	About 30 minutes prior to surgery you will be asked to take a pill by mouth. For 24 hours after your surgery, the study doctor and/or team member will monitor your progress and any pain you may have. No follow-up visits are required for this study.
Overview of Procedures	If you decide to take part in this study, a computer will assign you by chance to receive either the study drug (Baclofen) or a placebo (pill with no study drug in it). Descriptions of the procedures are provided in detail further below. After your surgery you will receive all normal post-operative care.After surgery, a study team member will review your medical records for the amount of pain medications you take during hospitalization, and your overall progress. The study doctor or team member will also ask you to rate any pain you may have after surgery.
Risks	If you decide to participate in this study, you may experience a side effect from taking the study medication, baclofen. You will be given a low dose (10 mg) of baclofen (lower than the 40-80 mg dose commonly used to treat muscle spasms). This lower dose may lower the chance of experiencing a side effect. Some of the common side effects of baclofen are: • temporary drowsiness • dizziness • weakness • confusion
Benefits	You may not benefit directly from taking part in this study. However, this study may help doctors understand how to provide better pain control after kidney stone surgery.
Alternatives	There are many options available for pain control after surgery if you decide not to participate in this study. The study doctor will discuss these options with you.

Purpose of the Research Study

We are asking you to take part in a research study. This research study will test if a medication (Baclofen) taken shortly before surgery reduces the pain after surgery. The purpose of this study is to evaluate how well a medication called Baclofen controls your pain after surgery. Your surgeon is aware of this study and has agreed that patients should be allowed to participate. We expect to enroll 86 patients.

Baclofen is a commonly used medication to treat muscle spasms. It has also been shown to help control pain after surgery in animal and human studies. However, no large study has been done to determine if baclofen reduces pain and/or need for pain medication immediately after surgery, therefore we can't say for sure how effective it is. The purpose of this study is to evaluate the impact of baclofen on pain after kidney stone surgery.

Explanation of Procedures

If you enter the study, you will be assigned to a group by chance (like the flip of a coin) to either receive the study drug (baclofen) or no medication (a similar pill that does not contain any medication, called a "placebo". You will not be told if you have taken the study drug or placebo.

- A study team member will meet with you on the morning of your surgery and confirm your decision to participate in this study.
- About 30 minutes before your surgery, while you are in the pre-operative holding area, the study team member will ask you to consume the pill by mouth.

All routine, standard care, including anesthesia and monitoring of your vital signs will be provided before, during, and after your surgery.

The amount of pain medication(s) given to you, any unexpected medical events, and your comfort will be assessed for 24 hours after your surgery. This will be done by obtaining information through your medical records and/or in person (for example, by talking with you). You will be asked to rate your pain score on a scale of 0 (no pain) to 10 (severe pain). You may also be asked if you are either nauseated or have vomited after your surgery. This will be performed once after your surgery, by a trained member of the study team. Any pain you may feel after surgery will be treated with the usual (standard of care) medications, as needed, whether or not you receive the study treatment.

Risks and Discomforts

If you decide to participate in this study, you may experience a side effect from taking the study medication, baclofen. You will be given a low dose (10 mg) of baclofen (lower than the 40-80 mg dose that is commonly used to treat muscle spasms). This lower dose may reduce the risks of side effects.

Risks Associated with Baclofen
Commonly reported side effects include: temporary drowsiness (10-63%), dizziness (5-15%), weakness (5-15%), confusion (1-11%), and nausea (4-12%). These side effects have been reported to be temporary and resolve on their own, without need for medical intervention. However, should you experience any of these symptoms, a doctor will fully evaluate you and determine if any treatment (such as medication to reduce nausea) is needed.

As with any medication, there is a small chance that you may experience an allergic reaction. The allergic reaction may range from a minor rash or runny nose to a more severe reaction causing difficulty in breathing, very low blood pressure, heart related problems, called anaphylaxis (< 1%). If this occurs, your specific symptoms will be treated with standard of care treatments and medications.

Benefits

You may not benefit directly from taking part in this study. However, this study may help us better understand how to provide better pain control for kidney stone surgery and reduce the recovery time after surgery.

Alternatives

The alternative is not to participate in this study. Irrespective of your decision to participate, any pain you may experience after surgery will be treated with the usual (standard of care) pain medications.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?
All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Who may use and give out information about you?
Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?
All individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research.

Information about you and your health which might identify you may be given to:
- the Office for Human Research Protections (OHRP)
- the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, University of Alabama Health Services Foundation, , as necessary for their operations; the UAB IRB and its staff
- the billing offices of UAB and UAB Health Systems affiliates and its billing agents

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution.

You may be removed from the study without your consent if the study doctor ends the study and/or decides it is not in the best interest of your health, or if you are not following the study rules.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There is no cost to you for participating in this study. The costs of your standard medical care will be billed to you and/or your insurance company in the usual manner. If you are in Medicare Advantage (Medicare managed care plan), you should contact someone at your plan before you start a clinical trial. They can provide more information about additional costs you could incur from participating in clinical trials.

Payment for Participation in Research

You will not be paid to participate in this study.

Payment for Research-Related Injuries

UAB has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

Significant New Findings

You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research or a research- related injury including available treatments, please contact Dr. Mandabach. He will be glad to answer any of your questions. Dr. Mandabach may be reached at (205) 975-9643 or after hours by paging him through the hospital operator, at 205-934-3411.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document.

Signatures

Your signature below indicates you that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

Signature of Participant

Date of Participant Signature

Signature of Legally Authorized Representative

Date of Legally Authorized Representative Signature

Relationship of Legally Authorized Representative

Signature of Person Obtaining Consent

Date of Person Obtaining Consent Signature

Non-Randomized Informed Consent And HIPAA Authorization

Record ID _____

INFORMED CONSENT FORM

TITLE OF RESEARCH: Baclofen as a Perioperative Analgesic Adjuvant for Kidney Stone Surgery (Baclofen)

IRB PROTOCOL: IRB-300002466

INVESTIGATOR: Dr. Mark Mandabach

SPONSOR: UAB Department of Anesthesiology and Perioperative Medicine

[redacted]

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of this study is to evaluate how well a medication called Baclofen controls your pain after kidney stone surgery.
Duration	About 30 minutes prior to surgery you will be asked to take baclofen by mouth. For 24 hours after your surgery, the study doctor and/or team member will monitor your progress and any pain you may have. No follow-up visits are required for this study.
Overview of Procedures	If you decide to take part in this study, you will be asked to swallow a pill (baclofen, 10 mg) by mouth about 30 minutes before surgery. After surgery, a study team member will review your medical records for the amount of pain medications you take during hospitalization, and your overall progress. The study doctor or team member will also ask you to rate any pain you may have after surgery.
Risks	If you decide to participate in this study, you may experience a side effect from taking the study medication, baclofen. You will be given a low dose (10 mg) of baclofen (lower than the 40-80 mg dose commonly used to treat muscle spasms). This lower dose may lower the chance of experiencing a side effect. Some of the common side effects of Baclofen are: • temporary drowsiness • dizziness • weakness • confusion • nausea
Benefits	You may not benefit directly from taking part in this study. However, this study may help doctors understand how to provide better pain control after kidney stone surgery.
Alternatives	There are many options available for pain control after surgery if you decide not to participate in this study. The study doctor will discuss these options with you.

Purpose of the Research Study

We are asking you to take part in a research study. This research study will test if a medication (Baclofen) taken shortly before surgery reduces the pain after surgery. The purpose of this study is to evaluate how well a medication called Baclofen controls your pain after surgery. Your surgeon is aware of this study and has agreed that patients should be allowed to participate. We expect to enroll 86 patients.

Baclofen is a commonly used medication to treat muscle spasms. It has also been shown to help control pain after surgery in animal and human studies. However, no large study has been done to determine if baclofen reduces pain and/or need for pain medication immediately after surgery, therefore we can't say for sure how effective it is. The purpose of this study is to evaluate the impact of baclofen on pain after kidney stone surgery.

Study Participation and Procedures

If you enter the study, a study team member will meet with you on the morning of your surgery and confirm your decision to participate in this study. About 30 minutes before your surgery, while you are in the pre-operative holding area, you will be asked to swallow a pill (baclofen, 10 mg)..

All routine and standard care (care that you would receive regardless of whether or not you are in this study), including anesthesia and monitoring of your vital signs will be provided before, during, and after your surgery.

A study team member will record the amount of pain medication(s) given to you, any unexpected medical events, for 24 hours after your surgery. This will be done by obtaining information through your medical records and/or in person (by talking with you). You will be asked to rate your pain score on a scale of 0 (no pain) to 10 (severe pain). You may also be asked if you feel nauseated or have vomited after your surgery. This will be performed once after your surgery, by a trained member of the study team. Any pain you may feel after surgery will be treated with the usual (standard of care) medications, as needed, whether or not you receive the study treatment.

Risks and Discomforts

If you decide to participate in this study, you may experience a side effect from taking the study medication, baclofen. You will be given a low dose (10 mg) of baclofen (lower than the 40-80 mg dose that is commonly used to treat muscle spasms). This lower dose may reduce the risks of side effects.

Risks Associated with Baclofen
Commonly reported side effects include: temporary drowsiness (10-63%), dizziness (5-15%), weakness (5-15%), confusion (1-11%), and nausea (4-12%). These side effects have been reported to be temporary and resolve on their own, without need for medical intervention. However, should you experience any of these symptoms, a doctor will fully evaluate you and determine if any treatment (such as medication to reduce nausea) is needed.

As with any medication, there is a small chance that you may experience an allergic reaction. The allergic reaction may range from a minor rash or runny nose to a more severe reaction causing difficulty in breathing, very low blood pressure, heart related problems, called anaphylaxis (< 1%). If this occurs, your specific symptoms will be treated with standard of care treatments and medications.

Benefits

You may not benefit directly from taking part in this study. However, this study may help us better understand how to provide better pain control for kidney stone surgery and reduce the recovery time after surgery.

Alternatives

The alternative is not to participate in this study. Irrespective of your decision to participate, any pain you may experience after surgery will be treated with the usual (standard of care) pain medications.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?
All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Who may use and give out information about you?
Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?
All individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research.

Information about you and your health which might identify you may be given to:
- the Office for Human Research Protections (OHRP)
- the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, University of Alabama Health Services Foundation, , as necessary for their operations; the UAB IRB and its staff
- the billing offices of UAB and UAB Health Systems affiliates and its billing agents

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution.

You may be removed from the study without your consent if the study doctor ends the study and/or decides it is not in the best interest of your health, or if you are not following the study rules.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There is no cost to you for participating in this study. The costs of your standard medical care will be billed to you and/or your insurance company in the usual manner. If you are in Medicare Advantage (Medicare managed care plan), you should contact someone at your plan before you start a clinical trial. They can provide more information about additional costs you could incur from participating in clinical trials.

Payment for Participation in Research

You will not be paid to participate in this study.

Payment for Research-Related Injuries

UAB has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

New Findings

You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research or a research- related injury including available treatments, please contact Dr. Mandabach. He will be glad to answer any of your questions. Dr. Mandabach may be reached at (205) 975-9643 or after hours by paging him through the hospital operator, at 205-934-3411.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this informed consent document.

Signatures

Your signature below indicates you that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

Signature of Participant

_____

Date of Participant Signature

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Signature of Legally Authorized Representative

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Date of Legally Authorized Representative Signature

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Relationship of Legally Authorized Representative

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Signature of Person Obtaining Consent

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Date of Person Obtaining Consent Signature

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