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Jun 18, 2020

**RESEARCH SUBJECT CONSENT FORM  
AND  
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION**

**TITLE:** A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel Group Phase 4 Study of the Efficacy and Safety of Patiromer for Oral Suspension in Combination with Standard of Care Treatment in Emergency Department Patients with Hyperkalemia

**SHORT TITLE:** Patiromer Utility as an Adjunct Treatment in Patients Needing Urgent Hyperkalemia Management (PLATINUM)

**PROTOCOL NO.:** CRA-US-001  
WIRB® Protocol #20201569

**SPONSOR:** Comprehensive Research Associates

**INVESTIGATOR:** Name  
Address  
City, State, Zip  
Country

**STUDY-RELATED  
PHONE NUMBER(S):** Phone Number  
Phone Number (24 hours)  
[24 hour number is required]

You are being asked for your consent to take part in a research study. This document provides a summary of this research. It describes the key information that we believe most people need in order to decide whether to take part in this research.

Please read this form carefully. Take time to ask as many questions about the study (also called, 'trial') as you would like. The study staff can explain words or information that you do not understand. Reading this form and talking to the study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form. You cannot take part in this research study if you do not sign this form.

**What should I know about this research?**

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled if you decide to not participate.

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- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled if you decide to withdraw your participation, even if you have already started participation.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

### **Why is this research being done?**

You are being asked to take part in a clinical research trial because you have been found to have an elevated potassium level in your blood, also known as hyperkalemia. The reason for the study is to find more effective treatments for elevated blood potassium. Clinical trials are a type of research to help doctors find ways to improve health and medical care.

This research study is being conducted by Comprehensive Research Associates. (CRA), also known as the study Sponsor. [Institution] is being paid by CRA to conduct this study.

The purpose of this research is to see if a drug, called patiromer, already approved by the U.S Food and Drug Administration (FDA), can help lower potassium while patients are in the emergency department.

Before you decide whether to take part, you should understand the possible benefits and risks associated with this study. You will be able to ask the staff any questions you may have. This consent form is designed to explain that information to you. Taking part in this study is entirely voluntary.

About 300 patients with hyperkalemia, across the US will take part in this research.

### **How long will I be in this research?**

If you decide to take part in the study, you will not be asked to spend time in the hospital that you would not be spending anyway due to your diagnosis of hyperkalemia (high potassium).

The treatment period, i.e., expected duration of the ED stay, is up to 1 day and the follow-up period is 14 days (+3 days). The total duration of your participation in the study is anticipated to be 15 days (about 2 weeks).

### **What happens to me if I agree to take part in this research?**

If you agree to take part, study staff will look at your records, ask you questions and may do a blood test to see if this study is right for you.

If this study is right for you, you will start the study. It will be decided by chance, using a computer, if you will receive active study drug (patiromer) plus standard of care treatment for your condition or placebo (not active) study drug plus standard of care of care treatment. You have an equal chance of receiving placebo or patiromer with standard of care treatment. During

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the research, you and your study doctor will not know which group you are in, but your doctor can find out in case of an emergency.

**Baseline:**

- The study drug will be given to you to take by mouth.
- The study staff will assess your overall health, review your medical history, signs and symptoms you had at check-in to the emergency room, including any medications you may be taking or have taken in the past 3 days.
- The study staff will record your blood pressure, breathing rate, pulse, temperature, the level of oxygen in your blood, height, and weight.
- Blood may be taken for testing if it was not already done as part of your routine care to check your general health
- If you are female and able to have children, a pregnancy test will be done.
- A 12-lead electrocardiogram will be done, if not already done as part of your care, this procedure records the electric signals in your heart. It is done by placing sticky pads on your chest and limbs and produces a paper tracing.

**Treatment**

The treatment phase will last until you leave the emergency department, receive dialysis (if needed) or have been in the emergency department for 10 hours.

- Your doctor will periodically check your electrolytes (like potassium) blood levels, every 2 hours (up to 5 times)
- A 12-lead electrocardiogram will be repeated 4 hours after taking study drug if you are still in the emergency department

**Day 1 (24 hours after taking study drug)**

When you depart the emergency department you will be given a packet of study drug powder to take with you. You will dissolve this powder in liquid and drink it 24 hours after you took the first dose of study drug, staff will explain what to do and they will give you the instructions in writing as well.

**Day 2 follow up (48 hours after taking study drug)**

You will be asked to return for a follow up visit. You will be asked at what time you took the second dose of study drug, and blood will be collected to check your electrolytes levels.

**Day 14 follow up**

Your study doctor will contact you or your family member by phone or may contact your regular doctor to check your health and discuss any health problems you may have had.

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### **HOW MUCH BLOOD IS TAKEN DURING THE STUDY?**

Blood samples will be collected during your stay in hospital as part of routine care, to allow your doctors to assess your medical status and make treatment decisions. In addition, blood samples will be taken for study-specific testing. The amount taken will not be more than 5 teaspoons.

### **What are my responsibilities if I take part in this research?**

If you agree to take part in this study, you must take the study treatment as instructed and do all study test and assessments. It is important that you follow the instructions from your study doctor. It is also important that you tell study staff about any other medicines, vitamins or herbal supplements you are taking before and during the study.

We do not know the effect of study drug on babies before they are born, or on nursing children. If you are female, you must not be pregnant or breast-feeding. Tell your study doctor if you are pregnant, are attempting to become pregnant or are breastfeeding. The randomization may take place before the result of the pregnancy test performed in this study is available. If the pregnancy test is positive you will discontinue treatment with study medication in the study. If you become pregnant during the study you should notify the study doctor right away.

You are not allowed to take part in any other research study while you are in this research study. If you have any health care contact such as with a doctor or a dentist, tell them that you are in this research study.

You should inform your study doctor or the study staff of any concerns you may have or any new health issues you may experience

### **Could being in this research hurt me?**

The study medication may cause side effects that we do not already know about. In previous studies people have had the side effects listed below. You may get none, some or all of these.

The most common side effects seen in clinical studies are:

- Constipation
- Hypomagnesemia (low magnesium level in blood)
- Diarrhea
- Nausea
- Abdominal discomfort
- Flatulence (passing gas)

It is also not possible to rule-out the chance of an allergic reaction to the study drug. Some symptoms of allergic reactions are mild (hives, itching) while others can be life-threatening (difficulty breathing, swelling of the throat), your study doctor will be closely watching your medical status for any side effects and will provide treatment as necessary.

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In addition, there are risks associated with some of the tests performed for the study, however, many of these tests are routine and would be performed anyway as standard care for patients who have abnormal electrolyte levels.

Risks associated with drawing blood samples:

- Fainting, or feeling light-headed
- Pain at the site where the needle is placed
- Swelling and bruising at the site where the needle is placed
- Rarely, there may be a small blood clot or infection at the site of the needle puncture.

While taking vital signs, the blood pressure cuff may also cause discomfort or bruising to the upper arm.

It is very important that you tell the study doctor and the study staff about any side effects that you might experience. You may experience side effects or discomforts that are not listed on this form.

Another non-medical risk is loss of confidentiality of your health information. Confidentiality of your health information is described the section titled “What happens to the information collected for this research?”

Your study doctor will tell you of any information learned during the study, including changes that might cause you to change your mind about taking part in the study.

### **Will it cost me money to take part in this research?**

You will not be charged to take part in the study. The study drug and all study-specific test and medical checks required by the study are provided at no cost to you.

### **Will being in this research benefit me?**

You may not receive direct medical benefit from receiving the study drug. It is possible if you are assigned to receive the study drug, it may help your hyperkalemia, but this is not guaranteed.

Just by taking part in this research study, you may be helping future patients by providing important information about the study drug and by contributing to medical knowledge.

### **What other choices do I have besides taking part in this research?**

Your participation in this study is voluntary. Your alternative to taking part is not to participate. If you choose not to participate, you will still be able to receive standard care for your disease, your usual medical care will not change. You can speak with your doctor or other healthcare professional regarding options and alternatives for treatment.

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### **What happens to the information collected for this research?**

Unless required by law, your name will not be disclosed outside the research institution. Your name will be available only to the following people or agencies: the study staff, Institutional Review Boards (IRBs; groups that ensure the study is run properly), health authority inspectors such as the U.S. Food & Drug Administration, and CRA (study monitors; people that review the study data and documents). The above-mentioned individuals will use the personal information collected as part of this study, including your medical records (“Study Information”) to check that the study is conducted correctly and to ensure the accuracy of the study information. These people are all obligated to maintain confidentiality by the nature of their work, and are bound by confidentiality laws. If required, the study doctor may contact your personal doctor to collect additional medical information and your past medical history.

The study doctor may only share your study information with people whom you have permitted to see it.

While participating in this study, the study doctor will replace your name with a special code to be associated with your information and that will be used for all the entities working to complete, monitor, and manage this study. All Study Information will be kept confidential within the limits of the law. If the results of this study are published or presented, you will not be named, and nobody will be able to tell that you were in the study from the publication or presentation.

Your participation in this study is voluntary and you may cancel this consent at any time and without any reason. If you do withdraw from the study, your participation will end and study staff will stop collecting information from you. However, CRA will continue to retain and use any research results that have already been collected. If you have withdrawn from the study, for safety reasons you may be asked to complete a final study assessment visit.

If you have any questions about the collection and/or use of your information or would like to exercise rights that you may have regarding this information, you should ask the study staff. If you wish to leave the study, please inform the study staff.

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

Data or specimens collected in this research will be de-identified and might be used for future research or distributed to another investigator for future research without your consent.

### **Who can answer my questions about this research?**

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

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This research is being overseen by an Institutional Review Board (“IRB”). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 562-4789, [help@wirb.com](mailto:help@wirb.com) if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

### **What if I am injured because of taking part in this research?**

If you are injured or get sick because of being in this research, call the study team immediately. The study team will arrange for you to receive emergency medical treatment. Your insurance may be billed for this treatment. The sponsor will pay any charges that are not covered by insurance policy or the government, provided the injury was not due to your underlying illness or condition and was not caused by you or some other third party. No other payment is routinely available from the study staff or sponsor.

### **Can I be removed from this research without my approval?**

The study staff, CRA, FDA, or the IRB may also decide to remove you from the study at any time without your consent. The study staff may choose to take you out of the study because of unexpected or serious side effects, or for other scientific, technical, logistical, or safety considerations.

Examples of why you may be taken out of the study are:

- Staying in the study would be harmful to you
- You need treatment that is not allowed in this study
- You failed to follow study instructions
- You become pregnant
- The study is cancelled

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

### **What happens if I agree to be in this research, but I change my mind later?**

Your participation in this study is strictly voluntary. You may refuse to take part in it, or you may stop participating at any time, even after signing this informed consent. There will be no penalty or loss of benefits to which you are otherwise entitled. However, if you decide to leave the study before it ends, the study staff will ask to see you before you are released from the study.

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If you decide to leave the study, you should tell the study staff as soon as possible. They will make sure that proper procedures are followed, and a final visit is made for your safety.

**Will I be paid for taking part in this research?**

CRA will refund reasonable expenses including travel or parking that you incur because of this study.

**DO I HAVE TO SIGN THIS HEALTH INFORMATION AUTHORIZATION?**

Yes, in order to participate in this study, you must authorize the release of your health information. If you do not agree, you cannot participate in this study.



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### Statement of Consent:

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

\_\_\_\_\_  
Signature of Research Subject able to consent      Date \_\_\_\_/\_\_\_\_/\_\_\_\_      Time \_\_\_\_:\_\_\_\_

\_\_\_\_\_  
Printed Name of Research Subject

### STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been and will be available to answer any questions the subject (or their family member) has about this study.

\_\_\_\_\_  
Signature and Name of Person Explaining Consent      Date \_\_\_\_/\_\_\_\_/\_\_\_\_      Time \_\_\_\_:\_\_\_\_

### IMPARTIAL WITNESS

If the person signing this consent form (Research Subject or their family member) is illiterate, an impartial witness must sign below. (Ideally, the witness should be selected by the subject or family member and should have no connection to the research team).

I have witnessed the accurate reading of the consent form to the research subject/ their family member, and the individual has had the opportunity to ask questions. I confirm the consent has been given freely.

\_\_\_\_\_  
Signature of Impartial Witness      Date \_\_\_\_/\_\_\_\_/\_\_\_\_      Time \_\_\_\_:\_\_\_\_

\_\_\_\_\_  
Printed Name of Impartial Witness

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## **HIPAA Authorization Agreement**

### **Permission to Review, Use and Release Information about You**

If you decide to be in this study, the study doctor and research team will use and share health data about you to conduct the study. Health data may include:

- Your name
- Address
- Phone number
- Date of birth
- Medical history
- Information from your study visits, including all test results

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the research team may share health data about you with authorized users. Authorized users may include:

- Representatives of Comprehensive Research Associates, including their affiliates and other vendors
- The Food and Drug Administration (FDA) and other US governmental agencies
- Governmental agencies of other countries
- The Institutional Review Board (IRB)
- Other authorized users

The Sponsor and those working for the Sponsor may use the health data sent to them:

- To see if the study drug works and is safe
- To compare the study drug to other drugs
- For other research activities related to the study drug

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy laws and could be further shared without your permission.

This permission will be good until December 31, 2070.

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You may take back your permission to use and share health data about you at any time by writing to the study staff. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign this form, you will not be able to take part in the study.

