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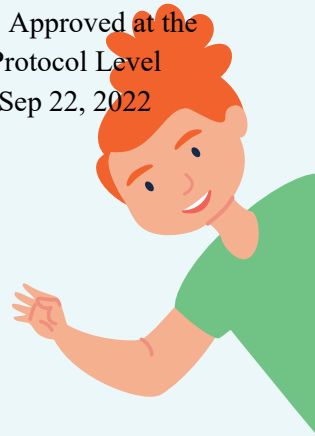

ADOLESCENT: Information for patients aged 12 to 17

The KANGUROO study of pediatric patients with neurogenic detrusor overactivity (NDO)

You may qualify to be part of research for NDO.

The KANGUROO Clinical Trial

What you should know about your participation in the KANGUROO study for adolescents with NDO

This flip chart will help you understand the KANGUROO study. You should review the informed consent form carefully before deciding to participate in this study.

Kanguroo

Introduction

- Patients are being asked to be in this clinical research study because they have NDO and are on clean intermittent catheterization
- Clinical research studies help doctors and researchers understand how investigational drugs work
- Investigational drugs are substances that have been approved to be tested on humans but are not yet available to the public. They are also called study drugs
- In this study, participants will take a study drug called vibegron
- Vibegron relaxes the muscle involved in normal bladder function
- Study doctors want to know how vibegron works for NDO in children
- The study will also look at how safe the study drug is
- If a participant agrees to be in our study, they will need to come to the study center at least 8 to 10 times
- Participants will have to record information about their urine (pee) volume and their sleep and wake times in a paper diary
- Participants will also have to record the date and time they take the study drug each day
- A study doctor or nurse will show participants how to complete the diary
- At doctor visits, the study staff will ask questions about the participant, their health, and how they are feeling
- Study staff will also do various tests such as physical exam, measurement of vital signs, ECG, blood and urine samples, PK samples, ultrasound, and Urodynamic assessment

Introduction

- You are being asked to be in this clinical research study because you have NDO and are on clean intermittent catheterization
- Clinical research studies help doctors and researchers understand how study drugs work
- In this study, you will take a study drug called vibegron
- The study will also look at how safe the study drug is
- During this study, you will come to the clinic at least 8 to 10 times
- You will have to record information about your urine (pee) and your sleep and wake times in a paper diary
- You will have to record the date and time you take the study drug each day
- At your doctor visits, you will answer questions about your health and how you are feeling. You will undergo some tests such as a physical exam (your heart, lungs, abdomen, and pelvis will be checked and your height and weight will be measured), measurement of your vital signs (heart rate, blood pressure, body temperature), ECG (to record the electrical activity of your heart), blood will be taken, urine (pee) will be collected, PK samples (blood is taken to examine how your body processes the study drug), ultrasound (a handheld wand attached to a machine is used to check your bladder and kidneys), and Urodynamic assessment (to measure your bladder function)

Do patients have to be in the study?

- Patients do not have to take part in this study
- If a patient does not want to be in the study, they should tell their parents/guardian or the study doctor
- If a patient signs the informed consent form (ICF), it means that they have read this form and that they want to be in the study
- Being in the study is up to the patient, and nobody will punish them or treat them differently if they do not sign the ICF or if they change their mind later
- If a patient starts the study but at a later time decides that they no longer want to be in the study, they can leave at any time, without having to say why
- Patients can ask questions about this study at any time
- Patients can also talk to their parent or guardian and ask to read the information the study doctor gives them
- Patients also may not qualify for continuing to take part in this study after the first visit
  - If this happens, the study doctor will explain why

Do I have to be in the study?

- You do not have to take part in this study
- If you do not want to take part, tell your parents/guardian or the study doctor
- If you sign the informed consent form (ICF), it means that you have read this form and that you want to be in the study
- Being in the study is up to you
- Nobody will punish you or treat you differently if you do not sign this paper
- You can change your mind later and decide that you no longer want to be in the study, without having to say why you want to leave
- You can ask questions about this study at any time
- You can ask your parent or guardian to read the information the study doctor gives them
- You may not qualify to continue to take part in this study after the first visit
  - If this happens, the study doctor will explain why

What will happen to participants in this study?

- Before any study-related tests and procedures can be done, an informed consent form must be read, understood, and signed by the parent or legal guardian and then a child assent form must be signed
- After these forms are signed, the study will begin with a screening visit. The purpose of the screening visit is to determine whether the participant meets the requirements to take part in this study. If study requirements are not met, the study doctor will explain why and will discuss other options
- The screening visit will last about 3 to 4 hours, but all other visits will last about 2 to 3 hours
- During the visits in which participant blood samples are collected, the study visit will last up to 9 hours (Part A) and up to 4 hours (Part B)
- The study is divided into 3 time periods: a screening/washout period, a treatment period, and a follow-up period
- During each study period, participants will have 1 or more visits with the study doctor at the center
- If the study doctor determines that the child meets all the requirements to be in this study, he or she will be assigned to receive either 50 mg or 75 mg of vibegron, depending on his or her weight. A dose reduction may be required based on how the child is doing, how their body is processing the study drug, and safety information. The study doctor will provide instructions.
- This study is open label, which means the parent, the child, the study doctor, and any other people involved in the study will know which dose of the study drug the child will receive
- The study doctor or study staff will give instructions on how to take the study drug. Participants will be given enough study drug to last until the next scheduled visit

What will happen to me in this study?

- Before any study tests and procedures can be done, an informed consent form must be read and signed by your parent or guardian and then a child assent form must be signed
- After these forms are signed, the study will begin with a screening visit. The purpose of the screening visit is to find out if you can be in this study. If you cannot be in this study, the study doctor will explain why
- The screening visit will last about 3 to 4 hours, but all other visits will last about 2 to 3 hours
- The study is divided into 3 time periods: a screening/washout period, a treatment period, and a follow-up period
- During each study period, you will have 1 or more visits with the study doctor at the center
- During the visits in which samples of your blood are collected, the study visit will last up to 9 hours (Part A) and up to 4 hours (Part B)
- If the study doctor determines that you meet the requirements to be in this study, you will be assigned to receive either 50 mg or 75 mg of vibegron depending on your weight. Your dose of study drug may be lowered based on how you are doing, how your body is processing the study drug, and safety information. The study doctor will tell you if your dose is lowered.
- This study is open label, which means you, your parent, the study doctor, and any other people involved in the study will know which dose of study drug you will receive
- The study doctor or study staff will tell you how to take the study drug. You will be given enough study drug to last until your next scheduled visit

How long will participants be in the study?

- Participants will be in this study for approximately 58 weeks
- Participants will come to the study center at least 8 to 10 times over this period
- Certain study assessments and procedures may be performed remotely, if authorized, during a pandemic or government-mandated stay-at-home order

How long will I be in the study?

- You will be in this study for approximately 58 weeks
- You will come to the study center at least 8 to 10 times during the study
- Some study assessments and procedures may be performed remotely (at home or by telephone), if authorized, during a pandemic or government-mandated stay-at-home order

Can anything bad happen to participants in the study?

Any study has risks, which may include things that could make the participant sick or uncomfortable or could harm the participant. All participants in the study will be watched carefully for any side effects; however, the study team does not know all the side effects that the study drug may cause. The study team may give the participant medicines to help reduce side effects. These side effects may be mild or serious. In some cases, these side effects might be long lasting or permanent and may even be life threatening.

Possible risks/side effects associated with the study drug:

- An increase in the participant's NDO symptoms if vibegron does not work for them
- Unpleasant side effects or reactions. The safety and effectiveness of vibegron have not been established in participants below the age of 18 years. The most commonly reported side effects in studies of vibegron with adult participants were headache, inflammation of the nose and throat, diarrhea, nausea, upper respiratory tract infection, dry mouth, constipation, increase in remaining urine volume in the bladder, hot flush, inability to completely empty the bladder, urinary tract infection (UTI), and bronchitis. Based on postmarketing experience evaluating vibegron, negative side effects that are considered "expected" include inability to completely empty the bladder, rash, itching, allergic drug reaction, itchy red and dry skin, and constipation
- Because the study drug is investigational, there may be risks and side effects that are unknown.
  All drugs have a possible risk of an allergic reaction
- During the washout period, participants may see an increase in their NDO symptoms

Can anything bad happen to me in the study?

Any study has risks. Some risks are things that could make you sick, make you feel uncomfortable, or harm you. Some, you might not notice at all. All participants in the study will be watched carefully; but the study team does not know all the side effects that the study drug could have on you. The study team might give you medicines to help reduce side effects. These side effects might be serious or mild (not very serious). For some people, these side effects could last a long time or be permanent. They could be life threatening.

Taking part in this study involves some risks and things that could make you uncomfortable.

Possible risks/side effects associated with the study drug:

- If vibegron does not work for you, your NDO symptoms could get worse
- The study drug may cause unpleasant side effects or reactions. Scientists do not know how safe vibegron is and how well vibegron works for participants less than 18 years old. When vibegron was studied in adults, the most common side effects that participants said they had, were headache, inflammation of the nose and throat, diarrhea, nausea, upper respiratory tract infection, dry mouth, constipation, more urine (pee) being left in the bladder, hot flush, inability to completely empty the bladder, urinary tract infection (UTI), and bronchitis. Some unpleasant side effects that are considered "expected" include inability to completely empty the bladder, rash, itching, allergic drug reaction, itchy red and dry skin, and constipation
- Because the study drug is investigational, there may be risks and side effects that are unknown.
  All drugs have a possible risk of an allergic reaction
- During the washout period, your NDO symptoms could get worse

Can anything bad happen to participants in the study? (continued)

Possible discomforts and risks associated with the study procedures:

- **Blood samples:** Taking blood from the participant's arm may cause faintness and/or swelling, pain, redness, bruising, bleeding, or infection (infection rarely happens) at the site where the needle is inserted. Study staff may use a special needle, called a "butterfly needle," to reduce the number of needle pricks. Study staff may also use anesthetic cream/paste to reduce pain at the injection site
- **Electrocardiogram (ECG):** Skin irritation is rare but could occur during an ECG from the electrode patches or gel that is used
- **Ultrasound:** Skin irritation is rare but could occur from the gel that is used
- **Urodynamic tests/assessments:** The participant may experience some or all of the following complications related to this procedure:
  - **Discomfort passing urine:** After the tests, some people feel a slight stinging or burning when they pass urine. If the participant drinks plenty of fluids for 24 hours after the tests, these symptoms should quickly settle. If discomfort lasts beyond this time, parents and/or participants should consult the study doctor because it may be a sign of infection
  - **UTI:** There is a small risk that an infection will be introduced into the bladder during the tests, despite measures (sterile equipment) to prevent this. If the participant thinks he or she has developed an infection, please consult the study doctor
  - **Blood in the urine:** After the tests, some people find a small amount of blood in their urine when they go to the toilet. If this lasts beyond 24 hours, parents and/or participants should consult the study doctor because it may be a sign of infection

Can anything bad happen to me in the study? (continued)

Possible discomforts and risks associated with the study procedures:

- **Blood samples:** Taking blood from your arm may cause faintness and/or swelling, pain, redness, bruising, bleeding, or infection (infection rarely happens) at the site where the needle is inserted. Study staff might use a special needle, called a "butterfly needle," to reduce the number of needle pricks. Study staff may also use a cream/paste that reduces pain at the injection site
- **Electrocardiogram (ECG):** Skin irritation is rare but could occur during an ECG from the electrode patches or gel that is used
- **Ultrasound:** Skin irritation is rare but could occur from the gel that is used
- **Urodynamic tests/assessments:** You might experience some or all of the following complications when you have urodynamic tests/assessments:
  - **Discomfort passing urine (peeing):** After the tests, some people feel a slight stinging or burning when they pass urine. If you drink plenty of fluids for 24 hours after the tests, these symptoms should quickly settle. If discomfort lasts beyond this time, please consult the study doctor because it may be a sign of infection
  - **UTI:** There is a small risk that you could get an infection in your bladder even though the study staff will try to prevent this (by using clean equipment). If you think you have developed an infection, please consult the study doctor
  - **Blood in the urine:** After the tests, some people find a small amount of blood in their urine when they go to the toilet. If this lasts beyond 24 hours, consult the study doctor because it may be a sign of infection

Can anything bad happen to participants in the study? (continued)

- **Symptoms or signs after use of topical anesthetic cream:** Topical anesthetic cream is considered very safe, and side effects are uncommon. Participants may, for a short amount of time, experience blurred vision, dizziness, vomiting, headache, muscle twitching, continuing numbness, weakness, or tingling. Participants may experience an allergic reaction or cyanosis, in which the skin becomes bluish due to poor circulation or inadequate oxygenation of the blood. In very rare cases, participants may experience a decreased rate of breathing and heart rate. Some symptoms of allergic reactions are rash/hives; wheezing and difficulty breathing; dizziness and fainting; swelling around the mouth, throat, or eyes; a fast pulse; or sweating. Parents and/or participants should seek medical attention immediately. As soon as they can, they should tell the study doctor and study staff if the child has any of these symptoms, or any other side effects, during the study

Can anything bad happen to me in the study? (continued)

- **Symptoms or signs after use of topical anesthetic cream:** Topical anesthetic cream is considered very safe, and side effects are uncommon. You may, for a short amount of time, have blurred vision, dizziness, vomiting, headache, muscle twitching, continuing numbness, weakness, or tingling. You can also experience an allergic reaction or cyanosis, where the skin becomes bluish due to poor circulation or not enough oxygen in the blood. In very rare cases, you may experience a decreased breathing and heart rate. Some symptoms of allergic reactions are rash/hives; wheezing and difficulty breathing; dizziness and fainting; swelling around the mouth, throat, or eyes; a fast pulse; or sweating. Please seek medical attention immediately. As soon as you are able, tell the study doctor and study staff if you have any of these symptoms, or any other side effects, during the study

Who can participants talk to about this study?

- Participants can ask questions about the study at any time
- Participants can call the study doctor any time at the phone number on the first page of the ICF
- If participants want to ask questions about what it means to be in a research study, they can call the Institutional Review Board/Institutional Ethics Committee, the group that oversees studies looking at test medications
- Participants can change their mind at any time
- Participants can stop being in the study at any time if they tell the study doctor, nurse, or their parent or guardian that they do not want to be in the study anymore

Who can I talk to about this study?

- You can ask questions about the study at any time
- You can call the study doctor any time at the phone number on the first page of the ICF
- You can change your mind at any time—just tell the study doctor, nurse, or your parent or guardian that you do not want to be in the study anymore