

# THE CLARITY STUDY

## INFORMATION SHEET

**Thank you for considering the CLARITY Study.** This information sheet might help address some questions you may have about taking part in this clinical study. However, if you have any further queries or concerns, please get in touch with the study team using the contact details at the end of this sheet.

Parents/legal guardians of minors – the following information indicates what the study means for your child. If your child is a minor, you will have a key role in helping them understand the study details, deciding whether they should take part and attending study visits with them. Please read this information sheet with or in place of your child as needed, knowing that 'you' and 'I' indicates what will happen for them. In some cases (such as contacting the study team), as a parent/guardian you will assume this responsibility.



### Q: What is a colonoscopy?

**A:** A **colonoscopy** is a medical procedure that allows a doctor to monitor or diagnose an illness in your colon. The colon is the lower part of the bowel and is commonly known as the **gut**.

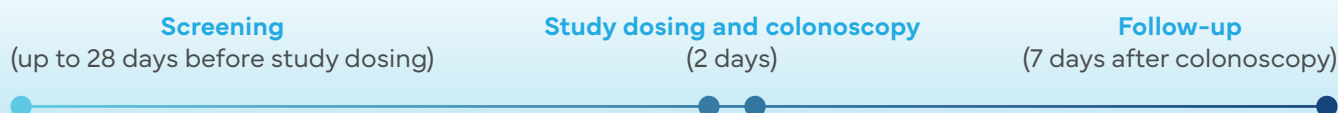
During a colonoscopy, the doctor looks inside your colon using a thin, flexible tube with a tiny camera on the end. To make sure the doctor has a clear view, your gut needs to be empty and clean. To achieve this, you must take a bowel cleansing drink before the procedure. As you have been recommended to have a colonoscopy, that procedure and the necessary bowel cleansing will be part of your routine care regardless of whether you take part in this study or not.

### Q: What is the purpose of the CLARITY Study?

**A:** This clinical study compares two bowel cleansing drinks. One is commonly prescribed to children and teens in preparation for a colonoscopy. The other is commonly prescribed for people aged 18 and over, and is now being tested for use by children and teens under 18 years of age (meaning it is 'investigational' in this age group). The CLARITY Study aims to find out which drink cleans the gut better, and which one is preferred by children and teens in terms of ease of use.

### Q: How long will I be involved?

**A:** You could be in the study for up to 39 days (5 weeks). This includes a Screening visit, when the study doctor checks whether the study is a good fit for you and if you can take part. The main part of the study (the bowel cleanse and colonoscopy) happens over 2 days, including an overnight stay at the study centre. A follow-up to check your wellbeing takes place 7 days after the colonoscopy and discharge from the study centre.



**Q: What are the two bowel cleansing drinks in this study?**

**A:** One is called **sodium picosulfate**. It is marketed as PICOPREP® or PICOLAX®. Doctors can prescribe this to children from the age of 1 year in some countries. The investigational bowel cleansing drink in this study is called **PLENVU®**. Permission has been granted for it to be given to children and teenagers in this study.

**Q: Which bowel cleansing drink will I receive?**

**A:** You have an equal chance of receiving PLENVU® or sodium picosulfate. This will be decided randomly by a computer. Randomly means something that is decided by chance, like flipping a coin. You will know which one you are taking. You will take one dose on the day before and one dose on the day of the colonoscopy. You will receive full guidance on how to take the drink.

**Q: What other study tests will I have?**

**A:** You will have various medical tests and assessments to check on your health and the effects of the bowel cleansing drink. These will include physical examinations; recording heart rate, blood pressure and body temperature; electrocardiograms (ECGs; to measure the heart's electrical activity); and collection of blood and urine samples. You will complete some questionnaires to find out what you feel about taking the bowel cleansing drink, as well as to record how much fluid you drink and how many times you have a bowel movement. The study doctor will rate how clear your gut appeared during the colonoscopy. The study centre will provide you with full details about your colonoscopy procedure.

**Q: Will I stay at the study centre?**

**A:** For the visit that includes study dosing and the colonoscopy, you will be checked into the study centre the day before your scheduled colonoscopy. You (and possibly also your parent/guardian) will stay there overnight and be able to leave the study centre a while after the colonoscopy has been completed. The Follow-up Visit may be scheduled as a phone call or as an in-person visit at the study centre.

**Q: Are there any other study commitments?**

**A:** On the day before the colonoscopy, you must have a 'low residue diet'. This means avoiding foods that are high in fibre or other residues that make it more difficult to clear the bowel completely. The study team will give you full information about which foods are suitable to eat and which ones to avoid.

**Q: Do I have to take part?**

**A:** No, participation is voluntary. You will only be able to take part if you give your consent. If you are considered a 'minor' in your location, your parent/guardian will also need to give their consent for you to participate. We are happy to provide you with the information needed to make an informed decision. You can withdraw from the study at any time without any penalty or loss of benefits to which you are entitled.

**Q: Will there be a charge for participating?**

**A:** The study bowel cleansing drink and study-related tests will be provided without charge. You may be reimbursed for your time and reasonable expenses associated with the study visits, such as travel and parking. A member of the study team can provide more details specific to your location.

**Q: How can I join?**

**A:** If you would like to be considered for the CLARITY Study, please contact us. We will be happy to give you more details about taking part and discuss next steps. Additional information about taking part is available on our website (parents/guardians of minors, please contact us or view the website on behalf of your child):



[www.theclaritystudy.com](http://www.theclaritystudy.com)



Contacting us does not mean that you must or will be able to join the CLARITY Study.

