

A CLEAR WAY FORWARD IN COLONOSCOPY

Parents/legal guardians of minors – this brochure provides a brief overview of 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 brochure with or in place of your child as needed, knowing that 'you' indicates what will happen for them.



STUDY
INFORMATION
BROCHURE



Study aim

Key to a successful **colonoscopy** is having a clean **gut**. The **CLARITY Study** is comparing two bowel cleansing drinks in **young people**:

- **PLENVU®** 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).
- **Sodium picosulfate** is commonly prescribed to children and teens in preparation for a colonoscopy.

This study aims to find out which one cleans the gut (colon) better, and which one is preferred by children and teens in terms of ease of use.



A **colonoscopy** is a medical procedure that allows a doctor to look inside your colon using a thin, flexible tube with a tiny camera on the end. The colon is the lower part of the bowel and is also known as the **gut**. 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.

We are looking for people to join this study who:



Are 1–17 years of age.



Need a colonoscopy.



Weigh at least 10 kg (1 stone 8 lbs).

Study treatment

If the study is suitable for you and you agree to take part, you will be randomly assigned to one of two study treatment groups. Randomly means something that is decided by chance, like flipping a coin. Your parent/guardian may also need to give their consent for you to take part.

You will have an equal chance of receiving either study bowel cleansing drink.

Key study facts

Study visits



**3 (1 may be by telephone)
with 1 overnight stay**

Type of study treatment



Solution taken by mouth

Dose duration



2 days

Overall study participation



Up to 39 days (5 weeks)

Participating regions



Europe

Study tests

As well as the colonoscopy, during the study you will have various medical tests and assessments. These will take place at the study centre or via telephone. Some of these tests will include:



Physical examination, including measurement of height and weight.



Measurement of heart rate, blood pressure and body temperature.



Electrocardiogram – a machine records the rate and rhythm of your heartbeats through small sticky patches attached to the chest, arms and legs.



Collection of blood and urine samples for various health checks.



You will fill in a questionnaire about how the study bowel cleansing drink tasted and felt in your mouth.

Your choice

Taking part is voluntary. You do not have to take part. If you do join, you can withdraw at any time for any reason.

Study contact

To find out whether you could be part of the CLARITY Study, please contact our study team. 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).



SCAN ME

www.theclaritystudy.com

