

CapaCiTY02 Study Site Feasibility Questionnaire

Introduction

As you may be aware, we will shortly be starting CapaCiTY study 2 (CapaCiTY02) at several sites across England. This is a clinical trial looking at Trans-anal irrigation (TAI) therapy in patients with chronic idiopathic constipation. This leaflet aims to give an overview of the proposed trial methodology and to ask how easy this would be to set up. We are especially interested to hear about your local practices in training and following up patients to use anal irrigation therapy. This will help us to design the study as appropriately as possible.

Study design

We will recruit patients who have chronic constipation and who have not responded to habit training or biofeedback therapy. Eligible patients will be randomised to use low-volume irrigation or high-volume irrigation. They will use one system for three months and their response will be analysed. After three months they may stop or switch to the other system and continue to be followed up. This is to assess whether one system is more effective than the other.

Training patients to use irrigation

This will be done as a face-to-face visit with an appropriately trained healthcare professional, who will demonstrate setting up the equipment and how it works, before supervising the patient set up the equipment. If possible, the therapist will observe the patient actually using the device. The therapist will contact the patient within two weeks to check everything is going well. If there are any problems then a further face to face visit can be offered. All patients will be followed up at 4 weeks (face to face or telephone call).

Reasons for switching therapy

This will be patient led and reasons for switching or discontinuing therapy will be recorded.

Reasons include:

Sensation of 'incomplete evacuation'
Frequent trips to the toilet
Need for repeated irrigation (≥ 3 times per day)
Satisfactory defaecation achieved with very low volumes ($< 300\text{ml}$)
No significant effect on symptoms or quality of life
The treatment is not acceptable to the patient
Patient experienced excess bloating
Patient experienced excess pain
Patient experienced anal leakage/incontinence
Other adverse event or technical difficulty experienced by the patient (please complete AE log)
Other reason (Please specify)

'Rescue therapy' and concomitant laxative use

It is inevitable that patients will wish to continue using laxatives. We propose the following allowed drug therapies alongside irrigation, to be used as needed:

- Bisacodyl tablets up to 20mg nocte
- Glycerine suppositories PRN
- Lactulose up to 15ml BD
- Movicol up to 2 sachets TDS
- Senna up to 15mg at night

Prokinetics (prucalopride, linaclotide, lubiprostone) will be strongly discouraged

Questionnaire

- 1) **What are your local procedures for starting patients on irrigation therapy and how do they differ from those outlined above?**
 - a. How many training sessions do you give?
 - b. How long are they?
 - c. What do training sessions involve?
 - d. How do you check patients are happy with using the device?
 - e. What short-term and long-term follow up do they get routinely?
- 2) **Would the proposed training procedure be acceptable to you, for example having patients demonstrate use of the system in clinic? If not, why not?**
- 3) **Which high volume and low volume systems do you use in your practice? Who prescribes them long-term (i.e. Hospital or GP)? Would there be any issue prescribing Peristeen rather than other high-volume systems?**
- 4) **What reasons, in your experience, do people give for switching/discontinuing therapy? Are there any additional reasons other than those listed above?**
- 5) **Do you agree with the proposed rescue therapy? If not, what would you consider acceptable?**
- 6) **Do you have sufficient resources available to allocate one blinded and one un-blinded researcher to collect data?**

Many thanks for taking the time to complete this questionnaire.