

Welcome to the first edition of the CIPHER newsletter!

We will use the newsletter to keep you up to date with study progress, breaking news and general reminders.

If you have items you would like to see covered in the next edition, please e-mail your suggestions to cipher-study@bristol.ac.uk.



A Message from the CIPHER Chief Investigator



Dear all,

The CIPHER study is a UK cohort study investigating the prevention of parastomal hernia (PSH). This is an important area of research looking at the incidence of symptomatic and radiologically confirmed PSH during a minimum of 2 years follow up. Additionally, CIPHER aims to evaluate the effects of key technical surgical steps during index stoma formation on the risk of subsequent PSH formation.



Thank you for all the hard work that has gone into setting up the study. We are pleased to announce that we started recruiting in January 2018 and the study is now open to recruitment at 27 sites across the UK.

Well done to all the sites that have recruited so far!

Yours sincerely,

Neil Smart
CIPHER Chief Investigator



Recruitment: Eligibility Criteria

It has come to our attention that there is some misunderstanding about the eligibility criteria.

Please note: We have purposely not specified the permanency of the stoma in the eligibility criteria as we want to be as inclusive as possible. We have specifically excluded loop ileostomies and double barrelled stomas as these are the ones we feel are most likely to be reversed.

If a patient fits the eligibility criteria, please include them regardless of how long you expect them to have their stoma!

Example scenarios of eligible patients:

Mrs XX, 65 years old with first presentation of severe ulcerative colitis. Meets a colorectal surgeon and stoma nurse early during her medical treatment by gastroenterology team. Despite best medical therapy for several days, her disease does not respond and after appropriate counselling the decision is taken to perform a subtotal colectomy and end ileostomy the following morning.

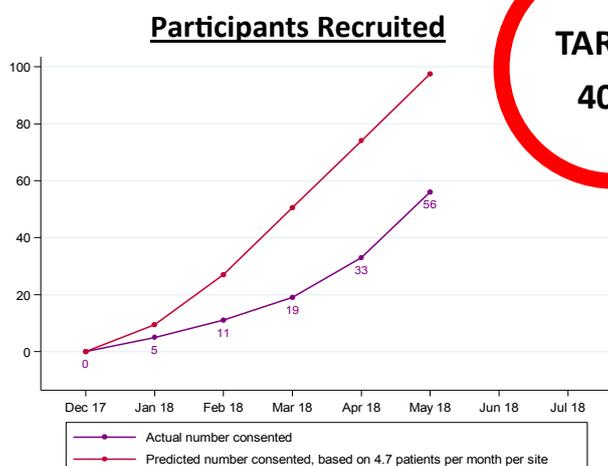
Mr XY, 75 years old with history of faecal incontinence following previous anal surgery 25 years ago. He has incomplete large bowel obstruction due to sigmoid stricture of uncertain nature despite multiple investigations and is not amenable to endoluminal colonic stenting. Third recent admission with worsening obstructive symptoms. Needs Hartmann's procedure in next 24 to 48 hours.

We are currently investigating the option of retrospective consent.

Recruitment Update

Number of participants recruited: 56

Number of sites open to recruitment: 27



All data present in the newsletter is accurate up until 31/05/2018.

SPOTLIGHT ON...

Queen Elizabeth Hospital King's Lynn (QEHKL)

We are proud to announce that Melanie Harding, a stoma care nurse specialist has taken on the role as Principal Investigator (PI) at QEHKL. This is the first CIPHER site to have a stoma care nurse in this role.

Involvement in research in the NHS is for all staff, not just a niche group. It is vitally important for patients that clinicians from all backgrounds engage in research, so that all phases of the care pathway can be improved. The CIPHER study was specifically designed with Stoma Care Nurses in mind – their relationship with patients with stomas is quite unique and absolutely critical to the success of life-changing, complex bowel surgery. No member of the multidisciplinary team is better placed than the Stoma Care Nurse to appreciate how the study fits into the local care structure – they are such an incredible resource.

We hope that other hospitals will also take this opportunity to widen participation in research.

"As stoma care nurse specialists we are very proud of the unique relationship we form with our patients and are looking forward to seeing the results of this interesting study."

Melanie Harding, PI at QEHKL



Stoma care nurses: Melanie Harding (left), Gill Skipper (right)



The Queen Elizabeth
Hospital King's Lynn
NHS Foundation Trust

Tips and Reminders!

- * **Screening Logs:** All patients who have an elective or expedited surgery to form an ileostomy or colostomy should be entered onto the screening log. This will give us a better understanding of the ineligible patients at your site.
- * **Data entry:** All data should be entered onto the database as soon as possible.
- * **Surgical data:** Data should be entered at the time of surgery, either in theatre or immediately after. These data are vital and are the reason the study exists.
- * **Database links:** Remember there are two different links to the database;
 1. the surgical database for which you must use your site's **generic log in details**
 2. the main database for which you must use your **personal log in details**
- * **General Data Protection Regulation (GDPR):** The new GDPR data protection laws came into force on the 25th of May, 2018. As a result, we have had to amend some of the wording in the patient information leaflet (PIL). **Please ensure you are using the new version of the PIL v4.0.** All sites will have received a new localised version.



Welcome to our most recent sites!

- ⇒ Plymouth Hospitals NHS Trust
- ⇒ Wirral University Teaching Hospital NHS Foundation Trust
- ⇒ Colchester Hospital University NHS Foundation Trust

Follow us
on Twitter!

@TheCIPHERStudy



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