
UK Cohort study to Investigate the prevention of Parastomal Hernia (CIPHER)

Record Status

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Citation

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Authors' objectives

Parastomal hernia (PSH) is a complication of surgery to remove some bowel with the creation of a stoma (with the end of the bowel passing through the side of the body and emptying bowel contents into a bag worn around the waist). PSH develops when the muscle in the body wall splits, causing a bulging of the skin next to a stoma. PSH develops quite often, affecting about 40% of patients within 2 years of their bowel surgery. Having a PSH makes it difficult to attach stoma bags which, in turn, causes bowel contents to leak, irritation of the skin and anxiety. PSH may also cause pain and, sometimes, unexpected hospital admissions to treat serious problems related to the hernia and bowel obstruction. Treatment is difficult and mostly involves specialist stoma care with expensive appliances; in some cases, further surgery may be required. Surgery for PSH, however, is associated with an increased risk of developing another hernia. Therefore, it is very important to prevent a PSH forming in the first place. Surgical methods for creating a stoma vary considerably but there is almost no high quality research evaluating whether the risk of a PSH is less with some methods than others. It has been suggested that the shape and size of the hole that the surgeon cuts in the body wall, whether or not a mesh is used and, if so, the type of mesh and where it is placed may be important. The lack of research about these variations in surgical methods means that it is not sensible currently to invest a lot of money in comparing just one or two surgical methods. Therefore, we are proposing a large study to find out what methods a large number of surgeons are using and the extent to which single factors, and combinations of factors, influence the risk of developing a PSH. This study will not be able to quantify accurately how much one particular factor can reduce the risk but it will identify key factors that need to be studied in a future randomised controlled trial. Our proposal is for a study of 4000 patients in 50 UK centres, involving surgeons who carry out operations in which they create a stoma. First, we will study a selected sample of operations and surgeons in-depth, to define precisely how their surgical methods vary. This will allow us to specify clearly the information we want to obtain in the subsequent, main study. In the main study, patients requiring surgery with formation of a stoma from the large or small bowel (colostomy or ileostomy) will be invited to take part. Joining the study will not affect patients' treatment but we will ask participants to complete questionnaires regularly over this period and seek their consent to study their outcomes a minimum of 2 years. This information will tell us how often PSH occurs. A study of this size will allow us to assess many surgical risk factors for PSH formation. We will also measure costs, health related quality of life, treatments given to reduce problems created by PSH and the rates of repeat surgery. This work will inform the design of a large trial to compare the effectiveness of different surgical methods to create a stoma, focusing on one or two specific factors identified by our study as being the most important for minimising the risk of a PSH developing. In the study an experienced team including patient representatives, specialist and academic surgeons and methodologists will work together linked to a surgical trials centre to deliver the work on time and target.

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