**Protocol for Randomised Controlled Feasibility Study comparing Cruroplasty with Circumferential DynaMesh-HIATUS**® **versus Suture-only Repair for Large Hiatus Hernias**

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**ABSTRACT**

**Purpose**

Laparoscopic fundoplication has become a standard surgical treatment for gastro-oesophageal reflux disease. Many of these patients also have a hiatus hernia that is repaired at the same time. However, suture-only repair of larger hiatus hernias have recurrence rates as high as 50%. Evidence on the effectiveness and safety of surgical mesh to reinforce hiatal repair compared to suture-only repair is currently lacking. This study aims to assess the feasibility of running a randomised controlled trial comparing the results of large hiatus hernia repair with DynaMesh-HIATUS® crural reinforcement versus standard suture repair alone.

**Methods**

This is a single centre, double blind, parallel group randomised feasibility study. Fortypatients with large hiatus hernia will be randomised to standard laparoscopic suture repair or suture repair with cruroplasty using the DynaMesh-HIATUS® circumferential mesh, with a three-year follow-up period. Participants and assessors will be blinded to treatment allocation. Outcomes include trial process indicators (eligible participants, recruitment and retention rates), surgical indicators (placement of mesh, operative complications, length of stay), adverse events, patient quality of life and symptom scores and mesh position after one year, and patient quality of life measures to 3 years.

**Results**

Feasibility will be assessed by rates of recruitment, retention and successful surgical procedures. Clinical and Patient-related outcomes for the two surgical methods will be described, and those most appropriate to include in a definitive trial identified. Correlation will be made between the position of the mesh on Magnetic Resonance Imaging (MRI) and clinical outcomes.

**Conclusion**

The DYNAMIC study will provide information to design and deliver a definitive randomised controlled trial of DynaMesh-HIATUS® cruroplasty compared to suture repair alone.

Trial registration number: <https://doi.org/10.1186/ISRCTN76437720>

**Key Words**: “hiatus hernia” “laparoscopic” “mesh” “cruroplasty” “randomised controlled trial”

**Sponsor and Funding**

The study is sponsored by Portsmouth Hospitals NHS Trust and will be delivered by the surgical research team and investigators from the Research and Innovation Department, Portsmouth Technology & Trials Unit, Portsmouth Hospital NHS Trust. The study is funded by the manufacturers of DynaMesh-HIATUS®, *FEG Textiltechnik (Germany).*

**Conflicts of Interest**

The study is funded by the manufacturers of DynaMesh-HIATUS®, *FEG Textiltechnik (Germany)* and their distributor *Hospital Services Ltd, Ireland,* including providing the mesh free of charge. They have no involvement in the delivery, data collection or analysis, and reporting of the trial. Simon Toh received sponsorship to present this proposed study at the European Hernia Society Conference in Hamburg, *Sept 2019*.

**Ethics**

Ethical approval was granted by South Central Berkshire B Research Ethics Committee on 10/06/2019 ref: 19/SC/0161.

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**INTRODUCTION**

 Laparoscopic anti-reflux surgery (LARS) for gastro-oesophageal reflux disease (GORD) is usually offered to patients for whom medical therapy is no longer effective, who cannot tolerate proton-pump inhibitors or who prefer surgery to avoid long-term pharmacotherapy (1,2). Most patients have a related hiatus hernia that is repaired with sutures at the same time. Over the past 20 years, laparoscopic techniques have been refined with higher day-case rates and better outcomes, making surgery an acceptable alternative to medical treatment (3). Several studies have shown that LARS is more cost-effective than medical therapy over time (2,4-8). The recent Cochrane systematic review demonstrated better GORD-specific quality-of-life outcomes and symptom control with surgery (9).

 Although LARS is effective for most patients with GORD, there is a cohort of patients with associated large hiatus hernias that have poorer outcomes. Hernia recurrence rates can be as high as 50% with standard suture repair, though this does include both small and large hernia recurrences. Revisional surgery for symptoms thought to be due to recurrence occurs in approximately 5% of patients (10,11). To mitigate this, some surgeons have tried modifications to the suture technique. One expert centre initially reported low recurrence rates of 6% with this, however this rose to 24% at 2yrs, and 50% by 10yrs (11-13). For these reasons, other surgical techniques have been sought to improve the durability of suture-only repairs, including Collis gastroplasty to lengthen the oesophagus and diaphragm-relaxing incisions (14).

 Another technique is to reinforce the hiatal repair with mesh, also known as mesh cruroplasty. Systematic reviews of both observational studies and randomised controlled trials investigating biological and synthetic meshes of varying designs, appear to have lower hernia recurrences in the short-term (15-17). However, reports of complications like mesh erosion needing major revision surgery have deterred surgeons from adopting mesh repair routinely for large hiatus hernias without more evidence of efficacy (18). Therefore, more long term studies of clinical, safety and patient-reported outcomes of any novel mesh repair of hiatus hernias are required.

This paper outlines the protocol for a feasibility study, to provide evidence for a definitive randomised controlled trial. This study aims to address the following questions:

1. Is it feasible to run a trial to compare laparoscopic anti-reflux surgery and large hiatus hernia repair with DynaMesh-HIATUS® mesh and suture versus suture alone (no mesh)?
2. What are the rates or average values of key outcomes for patients and health service providers for the two surgical methods, and which outcome is the most appropriate to power a definitive trial?
3. Is there any correlation between the magnetic resonance imaging (MRI) position of the mesh and clinical outcomes?

**METHODS**

**Study Design**

 DYNAMIC is a single centre feasibility study composed of a double blind, parallel group randomised controlled trial. This has been carefully designed as a *Stage 2b* Exploration Study using the *IDEAL Surgical Research Framework* (19). The study site is a tertiary-referral Oesophago-Gastric Surgical Unit within a large NHS District General Hospital in England.

**Participants and Sample Size**

The study population comprises of adults with large hiatus hernia (≥5cm in size\*) requiring surgery (for full eligibility criteria see **Table 1**).

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| Table 1. Eligibility criteria |
| Inclusion Criteria | **Exclusion Criteria** |
| * NHS patients undergoing elective laparoscopic repair of large hiatus hernias (≥5cm size\*) and fundoplication for gastro-oesophageal reflux disease or mechanical symptoms who fulfil criteria for keyhole surgery (i.e. fulfils standard indications and fitness for surgery)
* Aged 18 years and above
* Body mass index <40
* Able to provide written informed consent
 | * Concomitant medical condition likely to shorten survival to less than 1 year
* Previous hiatus hernia surgery
* Active treatment for any cancer
* Pregnancy
* Contraindication to MRI (incompatible metal implants, cardiac pacemaker or reveal devices)
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\* defined by ≥5cm diameter size (antero-posterior or transverse, whichever is greater) on CE-CT/Barium swallow or length of hiatus hernia of more than 5cm on endoscopy/CT/Ba swallow/manometry

This is a feasibility study to inform a future definitive randomised controlled trial and has been designed to test study procedures and to gain estimates and ranges for key outcome measures. It is not powered to detect a specific effect size for the use of the mesh during surgery. In line with sample sizes from other feasibility studies, we consider that 20 participants per group are sufficient to meet the feasibility objective. The team sees between 40-50 clinically eligible patients per year, and based on a consent rate of 50%, recruitment is estimated to be complete within 2 years.

**Recruitment**

Patients will be screened from referrals to specialist Upper GI clinic for consideration of anti-reflux surgery. They must meet the standard criteria for surgery, which can be either of the below:

1. GORD symptoms not responsive to best medical treatment for more than one year with at least Grade A oesophagitis *(Los Angeles Classification)* on endoscopy and/or a positive pH study (DeMeester Score>14.72) with adequate oesophageal motility on manometry and/or barium swallow.
2. Hiatus hernia (all types) with parts or all of their stomachs (and sometimes other organs) within the thoracic cavity – these patients can present with different symptoms including obstruction, volvulus, bleeding/anaemia, aspiration, shortness of breath and cardiac failure. They may not have had pH manometry (due to technical reasons) but would have had a barium swallow and/or Contrast Enhanced-Computer Tomography (CE-CT) scan instead.

Patients will be screened for eligibility criteria at their first consultation. If they are potentially eligible, the surgeon will introduce the option of joining the study during this consultation to the patient. They will ensure the necessary investigations have been completed (gastroscopy, oesophageal manometry/pH study and/or barium swallow, CE-CT scan). If the patient is fit and suitable for laparoscopic surgery, the surgeon will complete the routine pre-operative consent process and list them for surgery. Patients will be provided with the standard procedure information booklet and the Participant Information Sheet (PIS) for the study. If they have not had the appropriate investigations or need further work up such as an anaesthetic assessment or the need for dietary support to reduce weight, this will be organised by the surgeon before surgery.

**Randomisation**

A secure, online randomisation system [(https://www.sealedenvelope.com)](file:///%5C%5Cnasphthomes%5CUsers%5Cardarbyshire%5CDesktop%5CDYNAMIC%5C%28https%3A%5Cwww.sealedenvelope.com%29) will be used. Participants will be randomised using 1:1 randomisation and stratified by hernia size into two groups. Group 1 will have <50% stomach in chest (anticipated to be around 70% of the cohort), and group 2 ≥50% stomach in chest (anticipated to be around 30% of the cohort). Randomisation will be performed in the operating theatre, when the surgeon has measured the hernia size (both antero-posterior and transverse with estimate of percentage of stomach in chest) with a surgical tape measure in cm *and* plan to proceed with surgery. To monitor potential selection bias, any reason for non-randomisation when the patient has already consented to the study will be recorded and discussed within the trial management group at each occurrence.

**Treatment Groups**

Participants in both the intervention and treatment group will receive the same laparoscopic procedure to dissect and reduce the hiatus hernia sac and contents, and repair the oesophageal hiatus, using 0 Ethibond sutures in a standardised fashion with both anterior and posterior crural sutures around a 34 French bougie (3,12). Participants in the intervention group will also have the hiatal repair reinforced with DynaMesh-HIATUS® (choice of 2 sizes: 7x12cm or 8x13cm at discretion of surgeon). It is placed precisely encircling the oesophagus and secured in position with 2 x 0 Ethibond sutures to the right and left crus. Participants in the control group will receive the standard repair using sutures followed by an anterior 180o partial fundoplication. In the intervention group, the mesh will be placed and sutured to the crura before the fundoplication (see **Table 2.** for operative steps).

We did consider whether to include other techniques for repairing large hiatus hernias, such as oesophageal lengthening with a Collis gastroplasty and/or diaphragm-relaxing incisions (14). However, this would add confounding factors to the procedure. Furthermore, these techniques are not widely done as they require more advanced skills. On the contrary, the insertion of the mesh after suture repair was felt to be achievable in most centres without the need for surgical mentoring. Our early experience of this mesh with recurrent hernias suggests that it only takes about 10 minutes of additional surgical time (20). We did allow for a gastropexy as an optional step as this is often easy to do and could be useful to fix the stomach in the abdomen and reduce the risk of gastric volvulus (21). The procedures will be performed by two experienced consultant surgeons (SKCT, BCK) using this standardised technique and selected procedures will be recorded for review by an independent expert to ensure procedural integrity.

**Table 2.** Steps of laparoscopic hiatus hernia repair and fundoplication [11, 21, 22]

* Under general anaesthesia, a 34 French oral bougie is placed through the gastro-oesophageal junction and prophylactic co-amoxiclav or metronidazole and gentamicin (if penicillin allergic) is given intravenously after induction.
* 4-5 laparoscopic ports are inserted in an aseptic prepped abdomen, under direct vision, with a liver retractor (Nathanson or Endoflex). 12mmHg CO2 insufflation is used to create the space to perform the surgery.
* Surgeon uses a combination of diathermy scissors, hook or harmonic scalpel to dissect the hiatus displaying the right and left crus of the diaphragm, separating this from the hiatus hernia sac and contents which is carefully dissected and reduced, avoiding damage to the pleura. The vagus nerves are identified and preserved.
* The oesophagogastric junction is held with a Diamondflex retractor or rubber sling to allow for suturing of the crura, posteriorly and anteriorly using interrupted 0 Ethibond sutures until a snug repair is fashioned around the bougie. The looseness of repair is checked with a grasper alongside the oesophagus to ensure it is not too tight.
* The phreno-oesophageal ligament is re-sutured with O Ethibond sutures if this is possible.
* **Intervention Group Only:** the DynaMesh-HIATUS mesh is then inserted under aseptic conditions into the abdomen and placed precisely, lying as flat as possible the diaphragm, mobilising the left lobe of liver if needed to make space. It should encircle the oesophagus and be secured in position with 2 x 0 Ethibond sutures to the right and left crus. This video link illustrates the placement: <https://youtu.be/HC9aW5-8_RI>
* An anterior 180o partial fundoplication is then fashioned, usually using five 0 Ethibond sutures, two to the left crus and three to the right crus. In the intervention group, the mesh ends up sandwiched between the diaphragm and fundoplication.
* The wrap is carefully performed to ensure it is not too tight, using graspers to assess this. If it is appears too tight, an optional division of short gastric vessels is performed using a harmonic scalpel.
* Optional gastropexy may be performed using 2 -3 non-absorbable sutures to secure the stomach to the anterior abdominal wall.

DynaMesh-HIATUS® is a novel permanent synthetic circumferential mesh which is tailored specifically for hiatus hernia repair (**Figure 1**). The material polyvinylidene fluoride (PVDF) and its design are unique and have potential advantages compared to other meshes used for hiatal repair (22). These include:

* High effective porosity. This translates to less scarring and shrinkage compared to standard polypropylene mesh, reducing the risk of stenosis and erosion.
* It is less deformable under load, reducing the risk of erosion into the oesophagus anteriorly and posteriorly.
* It is a circumferential mesh reinforcing both anterior and posterior crural repairs, considered important in reducing recurrence (12).
* It has a smooth knitted margin, which should reduce the risk of erosion laterally.

**Outcome Measurements**

Outcomes for this study will be measured over the 3-year study period, assessing clinical, surgical and operative outcomes (See **Figure 2.** Study Flow Chart and **Table 2.** Outcome Measures). The patient and the assessor (research nurse) will be both blinded to the treatment arm for one year. The feasibility of the study will be assessed based on the ease of trial delivery and surgical process indicators. Outcomes for trial delivery include the number of eligible participants, proportion of patients consenting to the trial, and proportion of participants completing the study. As for surgical delivery, these are the number of patients with initial operation and follow-up period completed as per allocated treatment group.

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| Table 2. Outcome Measures |
| Clinical Outcomes  |  |
| * Quality of life using GERD-QOL and EQ-5D questionnaires (pre-operatively, 3-months, 6 months, then annual intervals 1-3 years)
* Post-operative recognised side effects of surgery: duration of resolution of dysphagia to solids, pain and gas bloat reported by patient and collated by research nurse (blinded)
* Length of hospital stay in days
* Time for patients to return to normal activities and work (in days)
* Patient safety and adverse events occurring peri- and post-operatively up to 1 year after surgery
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| Trial Delivery Outcomes | **Surgical Delivery Outcomes** |
| * Number of eligible participants
* Proportion of patients consenting into the trial
* Proportion of participants completing the study
 | * Number of patients with initial operation
* Follow-up period as per allocated treatment group
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| Operative Outcomes |  |
| * Operation time in minutes
* Blood loss during operation
* Position of mesh 1 year post-operatively using magnetic resonance imaging (MRI)
 | * Unplanned re-admission to theatre
* Size of hernia (in cm) on barium swallow pre-operatively and 1 year post-operatively
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Clinical outcomes focus on patient quality of life and recovery from surgery. These will be assessed using the Gastro-oesophageal Reflux Disease Health-related Quality of Life Questionnaire (GERD-QOL) specifically for acid reflux related symptoms; and the EuroQol-5D (EQ-5D) which is an internationally recognised, standardised non-disease specific instrument to describe and value health related quality of life (23,24). Patient-reported outcome measures (PROMS) will be completed pre-operatively and at 3 monthly intervals in the first year, and then annually until study completion at year 3. Recovery from surgery will be recorded in a patient diary for the first 10 days post-operatively, and every contact with the research team thereafter. This will document the recognised side effects of surgery: duration of resolution of dysphagia to solids, pain and gas bloat. If a patient has persisting symptoms of reflux at 1 year, then oesophageal manometry and pH study will be performed to evaluate degree of reflux with standard parameters.

Operative outcomes will address immediate peri- and post-operative complications, hiatus hernia recurrence and mesh position on MRI scan at 1 year. Barium swallow will be used to assess for hiatus hernia recurrence at 1 year from surgery; if it is abnormal then endoscopy will be performed to confirm this and document any evidence of oesophagitis. The mesh is uniquely visible on MRI scan and all the participants who received the mesh will have its position assessed 1-year post-surgery, unless they develop a contraindication to this. This will enable the relationship between mesh position and both clinical and symptomatic recurrence to be investigated [25].

Safety in each participant group will be assessed during surgery and up to 1-year post-surgery. This will be defined by any peri or post-operative adverse event. The only anticipated adverse device-related event could be excessive local scarring, that could result in difficulty swallowing and lead to rare complications like mesh erosion or infection. This will be identified from patients’ symptoms reported at follow up appointment or at any emergency admission; and confirmed with further imaging and endoscopic investigations. Rarely, a serious adverse event related to the mesh could result in the unblinding of the patient by the chief investigator, if this is deemed necessary for the care of that patient.

**Statistical Analysis**

Recruitment and retention rates for the study overall and in each arm will be calculated. Any adverse events occurring peri- and post-operatively up to 1 year after surgery will be described as the mean adverse events per patient and proportion of patients with adverse events. The nature and severity of serious adverse events will be described. Operative time and blood loss will be described using the mean; and unplanned re-admission to theatre will be given as a proportion. Time to resolution of side effects will be given as the mean and median. Length of hospital stay, and time for patients to return to normal activities and work will be recorded in days and described using the mean and median. Data analysis will be as per Intention-to-Treat, and all study participants will be included. We will calculate the mean differences between the two arms of the study as appropriate for the clinical, surgical and patient reported outcomes listed below along with their 95% confidence intervals. Data described will also be presented within the two randomisation strata (i.e. group 1: <50% stomach in the chest, group 2: ≥50% stomach in the chest).

**Data Monitoring**

An interim analysis will be performed when all participants have completed the last 12 month follow up visit (or MRI assessment, for those in the mesh group). Early termination of study will only be considered if there are more SAEs than expected related to the mesh and will be decided by the CI in discussion with the Sponsor and REC. Any protocol deviations will be discussed at each Trial Management Group meeting.

**Public and Patient Involvement**

The study protocol and PIS were discussed with our institution’s Patient Research Association (PRA) and presented at several of their meetings. Feedback on the study design, PIS and the patient diary was used to further amend the protocol, patient information and outcome measurement tools. The study was also discussed with our local Oesophageal Patients Association (OPA) a charity that supports patients with oesophageal cancer and their relatives. They have a vested interest in treatment of GORD, as it is a risk factor for oesophageal cancer. The chairman for the OPA has provided feedback on the study design and PIS; and will sit on the Trial Steering Group as the PPI representative, to help tackle any issues that arise during study implementation.

**Ethics**

Ethics approval was granted by South Central Berkshire B Research Ethics Committee on 10/06/2019 ref: 19/SC/0161.

**Dissemination**

The findings of this study will be disseminated to all groups who may benefit from the findings and could participate in future projects. It will be nationally presented in Association of Upper Gastro-intestinal Surgeons of Great Britain and Ireland (AUGIS) and/or British Society of Gastroenterology (BSG) conferences, and internationally at European Association of Endoscopic Surgeons (EAES), European Hernia Society or Digestive Diseases Week USA. The results will be published in a reputable peer-reviewed surgical journal and lay summaries disseminated through our OPA and PRA groups, and made available on our Research and Innovation website.

**DISCUSSION**

 Surgical mesh has been used routinely and very successfully in the management of hernias in many anatomical locations, for example, in the repair of inguinal hernias (25). However, hiatus hernias have posed a far greater surgical challenge, and investigated in a number of randomised controlled trials (RCT) comparing a diverse range of suture repairs with mesh to sutures alone. An initial RCT by *Frantzides* in 2002 had encouraging results, using a circumferential permanent polytetrafluoroethylene mesh to reduce early recurrence rates from 22% (8/36) to 0% (0/36, p=0.006), with only minor complications over a variable follow up period (mean 3.3years ± [SD 1.7]) (26). *Granderarth* used a small strip of polypropelene as an onlay mesh to buttress the sutured posterior hiatal repair, reducing intrathoracic wrap migration from 26% (15/50) to 8% (4/50, p=0.001), at the cost of higher rates of post-operative dysphagia in the 1 year follow up (27). *Oelschalger* investigated a biological mesh made from porcine small intestine submucosa (SIS) which was sutured in a U-shape over the crural repair. This reduced hernia recurrence of >2cm from 24% (12/57) to 9% (4/51, p=0.04) with a reduction in GORD symptoms and improved quality of life (QOL) in both groups (28). However, at 5 year barium swallow hiatus hernia had recurred in half of participants in each group, and difference in QOL diminished (29). *Watson* conducted the largest RCT comparing an absorbable SIS mesh (Surgisis®) to titanised-polypropelene (TiMesh®) and suture only repair; using the mesh as an onlay to buttress the posterior crural repair. No significant reduction in hernia recurrence occurred (30.8% [12/41] - absorbable, 12.8% [5/42] non-absorbable, 21.3% [9/43] - suture, p=0.161) with reduction in clinical symptoms small and variable. Recently published 5 year follow up demonstrates similar durability of repair to *Oelschalger’s* study, with hernia recurrence ranging from 39.3% to 56.7% (p=0.371), and worse symptoms with absorbable mesh repair (30). *Oor* used the same non-absorbable mesh as *Watson* (TiMesh®) but with a U-shape to buttress the posterior crural repair. There was no significant reduction in hernia recurrence (11.4% [4/36] vs 19.4% [6/36], p=0.37) with comparable QOL and dysphagia scores (31). While overall these studies provide some evidence to suggest that mesh cruroplasty can reduce hiatus hernia recurrence, those with long term follow up show that any benefit diminishes. It is worth noting that conducting 5 year barium swallow has its challenges, with 28% and 44% of the original study cohorts not undergoing the test, which may have affected the results.

Meta-analysis of these 5 RCTs found that need for re-operation was significantly higher with suture only repair (OR=3.26), but there was no significant difference in hernia recurrence (OR=1.65) (17). Recent meta-analysis, including RCTs and 2 cohort studies of high methodological quality, demonstrated no benefit of mesh cruroplasty over suture repair and identified substantial heterogeneity between studies (32). Inclusion of observational studies in two slightly older meta-analyses hinted at lower short term recurrences with mesh repair but long term outcomes were lacking, and these studies are at a greater risk of selection and detection bias (16,33). Additionally, all of these studies use a range of mesh materials (biological/permanent/hybrid) and designs (patch/circumferential/U-shaped) making results difficult to interpret. A systematic review looking exclusively at biological meshes versus suture repair showed only short-term benefit with similar recurrence rates over time (15). Therefore, although the evidence points to using a permanent, possibly circumferential mesh, as the best option, it remains poor and concerns over mesh complications has meant that most surgeons avoid mesh in this location, accepting a higher recurrence rate as the price to pay for a perceived safer suture repair (18). There is therefore a great need for high-quality studies of mesh repair that meet the best possible surgical research standards, as recommended by the Ideal Framework (19). To this end, advice was sought from experts to hone this study protocol during the Ideal Conference 2018 in Bristol, UK.

 We have therefore written this Dynamic study protocol to this high standard in the hope it can be used as a template for any future investigations of novel surgical intervention for the repair of hiatus hernias. This study investigates the feasibility of delivering a double blind, parallel group, randomised controlled trial comparing laparoscopic hiatus hernia repair with cruroplasty using a novel mesh (DynaMesh-HIATUS®) to standard suture repair. The results will inform us on the rates or average values of key outcomes for patients and the healthcare providers for the two surgical methods, and which outcomes are the most appropriate to power a definitive trial. This study aims to address potential methodological problems by using two validated quality of life questionnaires (GERD-QOL and EQ-5D) to quantify the patient’s recovery and allow for comparative analysis between intervention and standard procedure groups. We deliberately prioritise patient-reported outcomes (PROMs) above objective clinical measures, as the former are rightly the most important outcomes from hiatal hernia surgery (10). A challenge of this, and previous RCTs, has been that powering it to detect reduction in symptomatic recurrence would require a sample size in excess of 1000 participants. Thus, current studies have used radiological or endoscopic recurrence as a sensible surrogate primary outcome, given that significant reduction in hernia recurrence is likely to confer reduction in symptoms. We hope that by using robust measures of PROMs, it will enable us to plan a future multicentre trial powered to detect a clinically relevant outcome, with an achievable sample size. Finally, the 3-year follow up protocol should provide clarity on the longer term safety and durability of the repair.

 The potential benefits of the material and design of this mesh have already been alluded to above (20). We believe that the circumferential design and the ease of placement to be of particular advantage (22). This study will help establish if there are any immediate or late safety concerns for cruroplasty with DynaMesh-HIATUS®. The ability to visualise this mesh on MRI scan will permit correlation between patient’s symptoms and mesh position for the first time, allowing us to discern whether the patient’s symptoms are related to the mesh. Importantly, we hope it will reassure patients and their surgeons that mesh repair could be safe and feasible for large hiatus hernias, with the prospect of better long term results. Finally, this study will inform us on how to best proceed with a future larger multi-centre study.

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