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# The DYNAMIC Study - comparing standard stitch repair versus mesh-and-stitch repair of large hiatus hernias

**Submission date**
08/08/2018

**Recruitment status**
No longer recruiting

**Registration date**
19/11/2018

**Overall study status**
Completed

**Last Edited**
17/03/2020

**Condition category**
Digestive System

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English summary of protocol

Background and study aims
Heartburn caused by acid from the stomach passing upwards to the gullet (also known as 'reflux') is a common problem. This is due to a weakness or damage to a piece of muscle tissue, which covers the lower end of the gullet like a 'valve'. It is particularly common in people who have a hiatus hernia, a widening of the hole in a sheet of muscle in the abdomen (the diaphragm) through which the gullet connects with the stomach. Reflux that lasts a long time and is not treated can cause damage to the lining of the gullet that could lead to problems like difficulty swallowing and bleeding, and is linked to cancer in later life.
Reflux is usually treated with medicines that reduce acid levels, such as antacids. However, some patients still have symptoms despite this, and so are referred to hospital specialists to consider surgery. The surgeon usually repairs the hiatus hernia with stitches only and then fixes the valve by wrapping the top of the stomach around the gullet, known as 'fundoplication'.
Surgeons have been performing these operations since 1955, initially through a cut in the upper tummy, but nowadays using keyhole surgery. However, standard surgery using only stitches can fail in up to 50% of patients, as the hernia repair can weaken, meaning the hernia may come back. Sometimes, mesh implants are used, which helps to provide extra support to the damaged tissue. A new type of mesh, made of polyvinylidenefluoride (PVDF) has unique properties, which may help to improve the outcome of hernia surgery.
This study aims to look at the effectiveness of this new mesh, and how feasible it would be to carry out a larger trial of the mesh in future across many hospitals.

Who can participate?
Adult NHS patients undergoing elective keyhole repair of large hiatus hernias (more than 5 cm size) for heartburn at Portsmouth Hospital NHS Trust, who are suitable and fit for surgery (as assessed by the surgical team)

What does the study involve?
The study will randomise 40 patients to either standard stitch repair (20 patients) or stitch+mesh repair (20 patients) of their large hiatus hernias. This will be done using a computer programmed in the operating theatre once the patient is under anaesthetic. Neither the patient nor the nurse

assessing the patient afterwards will know if a mesh was used or not for one year. This will take away any bias in the study and make the results fairer.
Participants will be randomly assigned to receive either standard stitch repair or stitch and mesh repair once in the operating theatre after the participant is under anaesthetic. Participants will be asked to complete a diary about their recovery and, if they are suitable for MRI, will be asked to undergo an MRI scan one year after surgery.

What are the possible benefits and risks of participating?
The possible benefit of participating is that patients in the group receiving stitching and mesh pair may receive a more effective hernia treatment than the standard. All participants will closer follow-up treatment as a result of taking part.
The possible risk of taking part is that mesh hernia repair leads to a slightly higher risk of mesh erosion or infection, which could result in complications and further surgery. However, there has been no evidence of this with this particular mesh thus far. For participants in both groups, side effects (although unlikely) may include problems with swallowing and bloating.

Where is the study run from?
Portsmouth Hospital NHS Trust (UK)

When is the study starting and how long is it expected to run for? (what is the anticipated start date and the approximate duration of the trial?)
May 2017 to November 2021

Who is funding the study?
Dynamesh (Germany)

Who is the main contact?
Simon Toh
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# Contact information

### Type(s)
Public

### Contact name
Mr Simon Khay Chuan Toh

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
0002

# Study information

### Scientific Title
A randomised controlled feasibility trial of a novel polyvinylideneflouride (PVDF) mesh (DYNAMesh-hIatus) Cruroplasty versus suture only repair of large hiatus hernia

### Acronym
The DYNAMIC Study

### Study objectives
This study aims to address the following questions:
1. Is it feasible to run a trial to compare large hiatus hernia repair with Dynamesh and suture versus suture alone (no mesh)?
2. What are the rates or average values of key outcomes for patients and the NHS for the two surgical methods, and which outcomes are most appropriate to power a definitive trial?
3. Is there any correlation between the MRI position of the mesh and clinical outcome?

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Current ethics approval as of 15/07/2019:
Approved 10/06/2019, South Central - Berkshire B Research Ethics Committee (Whitefriars, Level 3, Block B, Lewins Mead, Bristol , BS1 2NT; 0207 1048310), ref: 19/SC/0161.

Previous ethics approval:
IRAS submission intended for September 2018 (reference: 231788)

### Study design
Interventional double-blind randomised controlled feasibility study

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

## Health condition(s) or problem(s) studied
Surgical repair of hiatus hernia

## Interventions
Participants are randomised into the intervention and control groups using the two-tier sealed envelope method in the operating theatre. Participants and outcome assessors will be blinded to treatment allocation.
Participants in the intervention group will receive hernia repair using insertion of Dynamesh®-HIATUS (choice of 2 sizes 7x12cm or 8x13cm at discretion of surgeon). during laparoscopic anti-reflux surgery, in addition to suturing. If participants in this group have no contraindications for MRI, they will have an MRI scan 1 year after surgery.
Participants in the control group will receive standard repair using only sutures.
For both groups there was a 3 year follow-up period. This will involve post-operative tests for pain, gas bloating and dysphagia 1, 5 and 10 days after surgery, and quality of life questionnaires after 3, 6 and 12 months and 2 and 3 years. Participants will be asked to keep a patient diary and perform a barium swallow test 12 months after surgery. If this is abnormal, participants will be asked to undergo an endoscopy and pH manometry.

## Intervention Type
Procedure/Surgery

## Primary outcome measure
1. Quality of life, assessed pre-operation, and 3 months, 6 months, 9 months, and 1, 2 and 3 years post-operation, using:
1.1. Gastro-oesophageal Reflux Disease Health-related Quality of Life Questionnaire (GERD-QOL)
1.2. EuroQol-5D (EQ-5D)
2. Size of hernia in cm, assessed using the barium swallow test pre-operation and 1 year post-operation
3. Mesh position, assessed 1 year post-surgery using magnetic resonance imaging (MRI)
4. Feasibility, based on trial delivery and surgery process indicators
5. Safety in each group during surgery and up to 1 year post-surgery

## Secondary outcome measures
1. The following trial indicators:
1.1. Number of eligible participants
1.2. Proportion of patients consenting to the trial
1.3. Proportion of participants completing the study
2. The following surgical indicators:
2.1. Number of patients with initial operation
2.2. Follow-up period completed as per allocated treatment group
3. Adverse events occurring peri- and post-operatively up to 1 year after surgery, collected using an approved Serious Adverse Events Case Report Form
4. Operation time in minutes
5. Blood loss during operation, assessed using a standard blood loss measurement using blood volume in ml from suction and swab weight
6. Unplanned re-admission to theatre, collected using an approved Serious Adverse Events Case Report Form by the research team, including timing, reason and outcome
7. Length of hospital stay in days, assessed using a Case Report Form by the research team

8. Time for patients to return to work/normal activities in weeks, assessed using a patient diary
9. Post-operative recognised side effects of surgery, assessed at the 3 month follow-up using a daily patient diary, including:
9.1. Duration of resolution of dysphagia to solids
9.2. Pain
9.3. Gas bloating

### Overall study start date
02/05/2017

### Completion date
01/11/2023

## Eligibility

### Key inclusion criteria
1. NHS patients undergoing:
1.1. Elective laparoscopic repair of large hiatus hernia (>5 cm in size)
1.2. Fundoplication for gastro-oesophageal reflux disease
2. Fulfil criteria for keyhole surgery
3. Aged 18 years or older
4. Body mass index <40 kg/m²
5. Able to provide written informed consent

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
40

### Key exclusion criteria
1. Concomitant medical condition likely to shorten survival to less than 1 year
2. Previous hiatus hernia surgery
3. Active treatment for any cancer
4. Pregnancy
5. Contraindications to MRI for supplementary MRI study (can still be recruited into the study, but not for the MRI study at 1 year), including:
5.1. Any metal implants
5.2. Pacemaker
5.3. Reveal devices

**Date of first enrolment**
30/07/2019

**Date of final enrolment**
01/11/2020

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Portsmouth Hospital NHS Trust**
Southwick Hill Rd
Cosham
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PO6 3LY

# Sponsor information

**Organisation**
Portsmouth Hospital NHS Trust

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**Sponsor type**
Hospital/treatment centre

**Website**
https://www.porthosp.nhs.uk/

**ROR**
https://ror.org/009fk3b63

# Funder(s)

### Funder type
Industry

### Funder Name
DynaMesh by FEG Textiltechnik Forschungs- und Entwicklungsgesellschaft mbH Prager Ring 70 D-52070 Aachen, Germany

# Results and Publications

### Publication and dissemination plan
We intend to publish the interim one-year results in a peer-reviewed scientific journal, present this at major national and local conferences, and make it available via our website. We will report the results in our local annual Portsmouth Hospital Research & Innovation conference and at a national surgical conference (e.g. AUGIS UK).

### Intention to publish date
01/11/2022

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from elaine.baddeley@porthosp.nhs.u. The anonymised dataset will be available from 1st November 2020 and will be kept for 5 years, and is only to be shared with any approved external review body for the purposes of governance or setting up a larger, hopefully NIHR-funded randomised controlled trial in future. As per GDPR, all data will be anonymised if it leaves the research department and only designated research team members will be allowed access to non-anonymised data. The study will be subject to IRAS approval prior to commencing.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |