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Sutureless mesh in inguinal hernia repair

Submission date 07/12/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 08/01/2009	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 03/05/2016	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims.
An inguinal hernia is a bulge in the groin, because of a weakness in the underlying muscle. A mesh (or patch) is placed over the area of weakness, deep to the skin. This strengthens the area and prevents the hernia recurring after the operation. The mesh that we currently use needs to be stitched to the underlying muscle. This is because the hernia would return if the mesh became displaced. However, some researchers believe that the stitches used to fix the mesh may be responsible for some of the pain experienced after the operation. It is normal to have some soreness immediately after the operation, and the pain-killers that we prescribe should keep it under control. However, some people seem to experience more pain than others. Also, some people may develop a condition called chronic groin pain after the operation. When this happens, the pain can last for weeks, and sometimes months. In other patients, there may be a persistent numbness in the groin. The new mesh does not need stitching, because it is designed to stick firmly to underlying tissues. Previous research has shown that this mesh is safe and effective. This research aims to find out if this mesh can reduce the incidence and severity of groin pain and numbness, and if it is as effective in repairing the hernia as the traditional mesh. The main aim is to investigate if the suture-less or self-gripping mesh produces chronic groin pain less frequently than the currently used mesh. Other aims are to study:
If the severity of pain immediately after the operation is reduced
If the incidence of groin numbness is reduced, and
If there is any difference in the recurrence rate of hernias.

Who can participate?
Patients over 16 years of age, who are due to undergo an open repair of an inguinal hernia.

What does the study involve?
Individual participants are randomly assigned to two groups: one group receives the sutured mesh, and the other receives the new mesh. You will not know which mesh you received until the end of the trial.
The entire process (pre-admission checks, admission to day ward, and discharge from hospital) will be the same whether you are participating in this study or not. However, if you are a participant, you will be given a questionnaire to complete, 4 6 hours after your operation. This questionnaire is called a McGill Pain Questionnaire. You will probably be discharged from hospital on the same day, but some patients need to remain in hospital overnight for a variety of reasons. Your participation in this study will not influence the decision of whether you get to go

home or remain in hospital overnight. Three months after your operation, you will be reviewed in the out-patients clinic. If you still experience any pain or numbness, you will be asked to fill in another pain questionnaire. One year after the operation, you will receive a telephone call from a member of the research team. The researcher will ask you a set of standard questions relating to the presence of pain, numbness, and swelling or lump in the groin. If you report that you do have pain, numbness, swelling or a lump, you will be invited to come to outpatients clinic for a check-up. We will check to see if your hernia has come back. If you still have pain, we will ask you to complete another pain questionnaire.

What are the possible benefits and risks of participating?
Though your participation may help in deciding if the new mesh is a significant advance in the treatment of hernias, there is unlikely to be any direct benefit to you. Also, though previous studies suggest that the new mesh causes less pain and numbness, these studies have been small and not as detailed as this study. Studies have already proved that the new mesh is safe and effective. However, we do not know if the new mesh is as reliable as the traditional one, in preventing a hernia returning. It is important to remember that you can get a recurrence even with the traditional mesh. This happens in approximately 2% (2 out of every 100) of operations performed.

Where is the study run from?
James Paget University Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
The study started in January 2009 and will end in December 2012

Who is funding the study?
James Paget University Hospital NHS Foundation Trust, Department of Surgery (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled single-blinded study of sutureless mesh repair of inguinal hernias

Study objectives
Does the use of a sutureless, self-adhesive mesh in the repair of inguinal hernia result in reduced postoperative pain and chronic pain? Does the use of such a mesh increase the risk of hernia recurrence?

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was submitted for an ethical review via NIHR Coordinated System on 07/12/2008, ref: 14211/17530/20/683

Study design
Randomised controlled single-blind single-centre trial

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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Open repair of inguinal hernia

Interventions
This is a randomised controlled single-blind (patients) trial.

For the study group, a Progrip™ mesh will be used. This is a lightweight mesh that does not have to be sutured in place, because its design incorporated microscopic 'hooks', which cause the mesh to adhere to tissues. The control group will receive an Ultrapro™ mesh. This is the currently used mesh, and is also a lightweight mesh. The only difference is that it needs to be secured in place by non-absorbable sutures.

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measures as of 12/12/2012:
Pain, measured using the SF McGill Pain Questionnaire 4-6 hours and 3 months after surgery

Previous primary outcome measures until 12/12/2012:
Pain, measured using the Visual Analogue Scale (VAS) score (0 = no pain, 10 = unbearable pain) 4-6 hours after surgery, at 6 weeks and 1 year.

Secondary outcome measures
1. Chronic groin numbness, as reported at 6 weeks and 1 year after surgery
2. Recurrence of hernia, as determined by telephone enquiry of all participants at 6 weeks and 1 year after surgery, and confirmed by physical examination of those reporting either 'lump' or 'swelling'
3. Operating time: as recorded from 'knife-to-skin' to completion of skin closure

Overall study start date
01/01/2009

Completion date
31/12/2012

Eligibility

Key inclusion criteria
All adult (both males and females, >16 years) patients who are to undergo conventional (open) repair of primary inguinal hernias. In general, all patients who are suitable for a conventional mesh repair are eligible for this trial.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

Key exclusion criteria

1. Refusal of consent (these patients will receive the standard sutured mesh repair)
2. Recurrent hernia and bilateral hernia

Date of first enrolment
01/01/2009

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
James Paget University Hospital NHS Foundation Trust
Great Yarmouth
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NR31 6LA

Sponsor information

Organisation
James Paget University Hospital NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.jpaget.co.uk

ROR
https://ror.org/04s7e3d74

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
James Paget University Hospital NHS Foundation Trust, Department of Surgery (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration