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Reinforcement of closure of stoma site using a biological mesh

Submission date
28/11/2012

Recruitment status
No longer recruiting

Registration date
30/11/2012

Overall study status
Completed

Last Edited
24/03/2021

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
An incisional hernia forms when a surgical wound fails to heal and a defect remains in the muscle wall. Closure of a stoma wound (stomas are formed when the bowel is brought to the tummy skin) is a frequent cause of incisional hernia, occurring in over 1,000 UK patients every year. Surgical repair of these hernias is hazardous and up to 1 in 2 repairs will fail. These patients can be elderly with multiple medical problems, so further attempts at repair may be too risky, meaning they must tolerate the symptoms of pain, swelling and discomfort and live with the risk of life-threatening complications. A treatment that reduces the occurrence of hernias after stoma closure would improve patients' quality of life, reduce surgical complications and remove the need for further operations. This study seeks to address this problem by the use of a mesh to support the wound while it heals. Meshes are widely used in hernia repair to support the muscles while they heal. However, the mesh increases the problems of infection when the wound is contaminated by bacteria (as is the case in stoma closure). We are using a type of 'biological' mesh made from animal tissue which is incorporated into the body tissues. Animal and human studies indicate that long-term infection problems are, as a consequence, reduced. Our preliminary study of 90 patients has shown this procedure can be performed safely. This study will test this new mesh against the standard procedure.

Who can participate?
Patients aged 18 or over undergoing an operation on their bowel to close their stoma.

What does the study involve?
Most of the treatment you receive will be the same as you would have received even if you were not in a study. There are no extra blood tests or operations required beyond your normal care and there are no additional clinic visits. You will also be asked to complete a short questionnaire about your quality of life before your operation, as well as a further questionnaire at 1, 12 and 24 months after your operation. You will then have your operation and will be randomly allocated to either have a mesh inserted at the time of surgery or have a standard stoma closure. You will not be told which group you are in so as not to influence the results in any way. After your operation you will receive the normal postoperative care, regardless of which group you are in. Once you have had your surgery we will need to collect information about the operation and any complications (e.g. how long the operation took, if there was any excess bleeding after

the operation, if you had any unexpected pain). You will be followed up in clinic and examined by a doctor to assess whether a hernia has developed. Most of this information will be collected at routine out-patient appointments. You will receive one follow-up telephone call around 9 months after the operation date to see how you are recovering and make sure you have not had any problems with wound infection or any other side effect. All information collected will be strictly confidential in the same way as your other medical records.

What are the possible benefits and risks of participating?
As part of the study, we will ask you to undergo a CT scan at 12 months after surgery. This CT scan is to assess if a hernia has developed which may not have been picked up by a routine clinical examination. This CT scan would be routine for some patients taking part in the study but will be additional for others. The scan involves radiation. The dose from a single CT scan is equivalent to about 3 years of natural background radiation. Any radiation is associated with an increased risk of developing cancer. However, the risk associated with a single CT scan is very small (about 1 in 3000) and negligible when compared with the 1 in 4 lifetime risk of cancer.

Where is the study run from?
Queen Elizabeth Hospital and 34 other hospitals in the UK, Netherlands and Denmark.

When is the study starting and how long is it expected to run for?
From October 2012 to August 2018

Who is funding the study?
LifeCell (USA).

Who is the main contact?
Prof Dion Morton
dion.morton@uhb.nhs.uk

Study website
http://www.birmingham.ac.uk/ROCSS

Contact information

Type(s)
Scientific

Contact name
Prof Dion Morton

Contact details
Academic Department of Surgery
School of Medicine
Queen Elizabeth Hospital
Edgbaston
Birmingham
United Kingdom
B15 2TH
-
dion.morton@uhb.nhs.uk

Type(s)
Scientific

Contact name
Dr ROCSS Trial Office -

Contact details
Birmingham Clinical Trials Unit (BCTU)
School of Health & Population Sciences
Public Health Building
University of Birmingham
Birmingham
United Kingdom
B15 2TT
+44 (0)121 415 9965
rocss@trials.bham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02238964

Secondary identifying numbers
13461

Study information

Scientific Title
A randomised controlled trial of Reinforcement Of Closure of Stoma Site using a biological mesh

Acronym
ROCSS

Study objectives
Abdominal wall hernias are common and are a significant cause of morbidity. Incisional hernias form following closure of the abdominal wall musculature. Incisional hernias at the site of stoma closure are not an infrequent problem, occurring in up to 30% of cases. Not only are they associated with adverse effects on patient's quality of life but in up to 10 % of cases, patients require complex reoperation associated with a high complication rate. It is for this reason that many patients choose to live with the hernia rather than undergo further surgery. Techniques that prevent the hernia from developing would improve the patient's quality of life and reduce the costs associated with redo surgery. Repair of incisional hernia commonly employs prosthetic meshes that reinforce and aid the tissue healing process. It is inappropriate to use synthetic mesh at site of previous stomas as there has been leakage of bowel contents that would infect the mesh and further compound the healing process. Many surgeons therefore choose to close the defect with sutures rather than using mesh. This may be a contributory factor in the

subsequent development of hernias. Biological mesh implants may be more suitable in these circumstances.

There is no evidence regarding the benefits of using biological mesh to prevent hernias at site of stoma closure. The balance of risks and benefits has not been reliably assessed in a randomised control trial. ROCSS is a randomised controlled trial of the placement of a biological mesh at the site of stoma closure. Our hypothesis is that reinforcing the stoma closure site with a collagen mesh (Strattice®) is superior to the standard technique in preventing herniation at 2 years.

More details can be found at: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=13461
Protocol can be found at: http://www.birmingham.ac.uk/Documents/college-mds/trials/bctu/rocss/ROCSS-Protocol-v4-08Oct2014.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - Coventry & Warwickshire; conditional approval was given on 04/07/2012 with confirmation of compliance with the conditions received on 07/08/2012, ref: 12/WM/0187

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Oral and Gastrointestinal, Generic Health Relevance and Cross Cutting Themes; Subtopic: Oral and Gastrointestinal (all Subtopics), Generic Health Relevance (all Subtopics); Disease: Gastrointestinal, Surgery

Interventions
Reinforcement of the stoma closure site using the Strattice® collagen mesh.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Recruitment at 12 months

Added 03/06/2015:
Full phase III:
Rate of clinically detectable hernias at two years post-randomisation.

Secondary outcome measures
Added 03/06/2015:
Full phase III:
1. Radiological hernia rate at 1 year post-randomisation. An exploratory analysis will also compare radiological hernia rate at 1 year with clinical hernia rate at 2 years to assess the value of using a CT scan as an early diagnostic tool of incisional hernias
2. Incidence of developing a symptomatic hernia evaluated at 12 and 24 months post-randomisation. The clinical detection of hernias defined by palpable fascial defects, and global weaknesses around closed stoma sites without palpable fascial defects, will be recorded. Patient-reported hernia symptoms including a local lump or pain at the site of the stoma closure will also be collected
3. Surgical re-intervention rates at 2 years post-randomisation
4. Surgical complications, including wound infections and seroma formation, at 30 days post-operatively and at 1 year post-randomisation
5. Quality of life assessed using EuroQol EQ-5D at baseline, 30 days post-operatively, 12 and 24 months post-randomisation
6. Pain assessed using a 100-point visual analogue scale at baseline, 30 days post-operatively, 12 and 24 months post-randomisation

Added 10/01/2017:
7. Costs per hernia clinically detected at 2 years post-randomisation
8. Two-year and long-term costs per additional quality adjusted life (QALY) year gained

Overall study start date
29/10/2012

Completion date
01/08/2018

Eligibility

Key inclusion criteria
Patients to be included in the study must:
1. Require an elective closure of stoma site
2. Have given written informed consent
3. Male & Female, aged 18 or over
4. Agree to the randomised procedure

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
790

Total final enrolment
790

Key exclusion criteria
1. Patients taking part in another clinical study which directly relates to the surgical procedure
2. Allergic to any porcine or collagen products
3. Unable or unwilling to provide written informed consent

Added 03/06/2015:
4. History of familial adenomatous polyposis, due to increased risk of desmoid tumours
5. The surgeon determines that a mesh repair will definitely be required e.g. due to large parastomal hernia

Date of first enrolment
20/11/2012

Date of final enrolment
30/10/2015

Locations

Countries of recruitment
Denmark

England

Netherlands

United Kingdom

Study participating centre
Queen Elizabeth Hospital
Birmingham
United Kingdom
B15 2TH

Study participating centre

34 other hospitals
United Kingdom
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Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Edgbaston
Birmingham
England
United Kingdom
B15 2TT

Sponsor type
University/education

Website
http://www.birmingham.ac.uk

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Industry

Funder Name
LifeCell

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
Research for Patient Benefit - NIHR

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/08/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	feasibility study results	01/09/2016	10/04/2019	Yes	No
Results article		08/02/2020	24/03/2021	Yes	No