ISRCTN25584182 https://doi.org/10.1186/ISRCTN25584182

Reinforcement of closure of stoma site using a biological mesh – extended follow-up

Submission date
28/04/2022

Recruitment status
No longer recruiting

Registration date
10/05/2022

Overall study status
Completed

Last Edited
12/08/2024

Condition category
Surgery

[_] Prospectively registered
[X] 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. The ROCSS study sought 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). In ROCSS a type of 'biological' mesh made from animal tissue which is incorporated into the body tissues was used. Animal and human studies indicate that long-term infection problems are, as a consequence, reduced. ROCSS showed ROCSS was that fewer patients in the mesh group had a detectable hernia after 2 years – nearly half the number of participants compared to those who did not get a mesh.
The ROCSS study was trying to find out if the mesh works or not at reducing the development of hernias. We believe that more people will form hernias over time, and these may require treatment and impact of peoples' quality of life. We aim to investigate this in the ROCSS-EX study.

Who can participate?
Patients who took part in the original ROCSS study in the UK who successfully has their stoma reversed.

What does the study involve?
ROCSS-EX does not involve any additional treatment, tests or hospital visits. The extend follow-up involves a one-off telephone consultation to ask questions about quality of life the reversal

operation and any symptoms related to the abdominal wall. It will also involve a review of health records to assess if any additional treatments may have been required in relation to the closed stoma site, reducing the number of questions asked during the telephone consultation.

What are the possible benefits and risks of participating?
There are no risks associated with taking part as this study involves only a telephone consultation.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
November 2020 to August 2022

Who is funding the study?
National Institute for Health and Care Research (NIHR) Research for Patient Benefit (RfPB) (NIHR212020) (UK).

Who is the main contact?
Ruth Evans, Trial Manager, rocss@trials.bham.ac.uk

Study website
https://www.birmingham.ac.uk/ROCSS-EX

Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
077075

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 49449, NIHR202011, IRAS 077075

Study information

Scientific Title
Extended follow-up of the ROCSS trial

Acronym
ROCSS-EX

Study objectives
Is there a significant improvement in long-term quality of life for patients that have a biological mesh reinforcement of the abdominal wall at the time of closure of stoma site, and is the intervention cost-effective?
An extended follow up of the ROCSS study (https://www.isrctn.com/ISRCTN46330337)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/01/2021, West Midlands - Coventry & Warwickshire Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 207 104 8009; coventryandwarwick.rec@hra.nhs.uk), ref: 12/WM/0187

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Not specified

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
Incisional hernia

Interventions
There is no intervention if ROCSS-EX as such as it extended follow-up – the intervention under investigation remains the same one as in the original ROCSS trial (Reinforcement of the stoma closure site using the Strattice® collagen mesh). (https://www.isrctn.com/ISRCTN46330337)

Intervention Type
Other

Primary outcome measure
Quality of life at 5 to 8 years following closure of stoma site comparing participants who had mesh reinforcement of their abdominal wall with participants that had a standard closure. This will be assessed using the HerQLes tool

Secondary outcome measures
At 5-8 years follow-up:
1. Participant reported incisional hernia rate
2. Number of hospital visits for any hernia related reason
3. Number of interventional procedures related to the stoma closure site or hernia
4. Longitudinal QoL assessed using EQ-5D
5. Cost analysis for all additional hernia related events

Overall study start date
01/11/2020

Completion date
31/08/2022

Eligibility

Key inclusion criteria

All participants included in the ROCSS trial are eligible to be included in ROCSS-EX unless they withdrew or did not have their stoma reversed during the duration of the original trial. those participants who have died, only routinely collected data will be used.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 702; UK Sample Size: 702

Total final enrolment
406

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/02/2021

Date of final enrolment
31/05/2021

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Heartlands Hospital
Bordesley Green East
Bordesley Green
Birmingham
United Kingdom
B9 5SS

Study participating centre

Bristol Royal Infirmary
Marlborough Street
Bristol
United Kingdom
BS2 8HW

Study participating centre
Broomfield Hospital
Court Road
Broomfield
Chelmsford
United Kingdom
CM1 7ET

Study participating centre
Chesterfield Royal Hospital
Chesterfield Road
Calow
Chesterfield
United Kingdom
S44 5BL

Study participating centre
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre
Dorset County Hospital
Dorset County Hospital
Princes Street
Dorchester
United Kingdom
DT1 1TS

Study participating centre
James Paget University Hospital
Lowestoft Road
Gorleston

Great Yarmouth
United Kingdom
NR31 6LA

Study participating centre
King's Mill Hospital
Sherwood Forest Hospitals NHS Foundation Trust
Mansfield Road
Sutton-in-Ashfield
United Kingdom
NG17 4JL

Study participating centre
Leicester General Hospital
Gwendolen Road
Leicester
United Kingdom
LE5 4PW

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Macclesfield District General Hospital
Macclesfield District Hospital
Victoria Road
Macclesfield
United Kingdom
SK10 3BL

Study participating centre
Manor Hospital
Moat Road
Walsall
United Kingdom
WS2 9PS

Study participating centre
New Cross Hospital Royal Wolverhampton
Wolverhampton Road
Heath Town
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Pilgrim Hospital
Sibsey Road
Boston
United Kingdom
PE21 9QS

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

Study participating centre
Queen Elizabeth the Queen Mother Hospital
St. Peters Road
Margate
United Kingdom
CT9 4AN

Study participating centre
Queens Medical Centre
Nottingham University Hospital
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre

Raigmore Hospital
Old Perth Rd
Inverness
United Kingdom
IV2 3UJ

Study participating centre
Royal Albert Edward Infirmary
Wigan Lane
Wigan
United Kingdom
WN1 2NN

Study participating centre
Royal Stoke University Hospital
Newcastle Road
Stoke-on-trent
United Kingdom
ST4 6QG

Study participating centre
Royal United Hospital Peasedown
Roman Way
Bath Business Park
Peasedown St. John
Bath
United Kingdom
BA2 8SG

Study participating centre
Salisbury District Hospital
Salisbury District Hospital
Odstock Road
Salisbury
United Kingdom
SP2 8BJ

Study participating centre
Sandwell General Hospital
Lyndon
West Bromwich

United Kingdom
B71 4HJ

Study participating centre
St Marks Hospital
Watford Road
Harrow
United Kingdom
HA1 3UJ

Study participating centre
St Richards Hospital Laboratory
St. Richards Hospital
Spitalfield Lane
Chichester
United Kingdom
PO19 6SE

Study participating centre
University Hospital Coventry & Warwickshire
Clifford Bridge Road
Walsgrave
Coventry
United Kingdom
CV2 2DX

Study participating centre
University Hospital of North Tees
Hardwick Road
Stockton-on-tees
United Kingdom
TS19 8PE

Study participating centre
The Worcestershire Royal Hospital
Newtown Road
Worcester
United Kingdom
WR5 1ZL

Study participating centre
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9LT

Study participating centre
Yeovil District Hospital NHS Foundation Trust
Yeovil District Hospital
Higher Kingston
Yeovil
United Kingdom
BA21 4AT

Study participating centre
York Hospital
Wigginton Road
York
United Kingdom
YO31 8HE

Study participating centre
Norfolk & Norwich University Hospital
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Sponsor information

Organisation
University of Birmingham

Sponsor details
Edgbaston
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United Kingdom

B15 2TT
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researchgovernance@contacts.bham.ac.uk

Sponsor type
University/education

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

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/06/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Manjinder Kaur (m.kaur@bham.ac.uk/rocss@trials.bham.ac.uk) . Access to anonymised data may be granted following review.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 8.0	12/01/2021	30/08/2022	No	No
Results article		02/08/2024	12/08/2024	Yes	No