A randomised controlled study to compare the use of Permacol™ for repair of parastomal hernias with current treatment with either synthetic mesh or primary suture repair

Submission date	Recruitment status	Prospectively registered
10/09/2004	Stopped	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
21/09/2004	Stopped	Results
Last Edited	Condition category	Individual participant data
30/06/2011	Surgery	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

PR700

Study information

Scientific Title

Study objectives

Parastomal hernias are protrusions of the abdominal viscera adjacent to a stoma. Most parastomal hernias develop in the first few years after stoma formation but there is an on-going risk, especially in patients with risk factors such as obesity and raised intra-abdominal pressure. Parastomal hernias may be asymptomatic but they frequently cause difficulty with fixation of the stoma appliance resulting in leakage. There is also a risk of strangulation, which can cause intestinal obstruction.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Parastonal hernia

Interventions

There is no standard method to repair parastomal hernias. Some surgeons use primary repair which involves suturing the patient's tissue directly with suture material, whereas others prefer to use a surgical implant of varying types to strengthen the repair. These repairs are not without problems.

Permacol™ surgical implant is a flat sheet of porcine dermal collagen. It carries the class III CE mark and FDA clearance and is fully licensed for permanent implantation into humans. It has been successfully implanted in over 75,000 patients worldwide since 1998, in a variety of surgical procedures. Permacol™ has already been used to successfully repair parastomal hernias. This study will investigate the feasibility of implanting a sheet of Permacol™ around the stoma to repair the parastomal hernia and compare the results with the preferred method of each hospital.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

Completion date

31/12/2004

Reason abandoned (if study stopped)

Lack of funding and participant recruitment issues

Eligibility

Key inclusion criteria

Patients must have a symptomatic parastomal hernia; be aged over 18 (or the country applicable age of consent); if of child-bearing age must have given a negative pregnancy test; give written informed consent; agree to be randomised.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

Key exclusion criteria

Patients must not be taking part in another clinical study; not be suffering from an UNTREATED metabolic or systemic illness (e.g. diabetes or rheumatoid arthritis); not have a diagnosis of mentally limiting conditions such as Alzheimer's or mental retardation or be unable to understand all study requirements; not be allergic to any porcine or collagen products.

Date of first enrolment

01/01/2004

Date of final enrolment

31/12/2004

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Colorectal Surgical Unit Bradford United Kingdom BD9 6RJ

Sponsor information

Organisation

Tissue Science Laboratories plc (UK)

ROR

https://ror.org/020hbh524

Funder(s)

Funder type

Industry

Funder Name

Tissue Science Laboratories plc (UK) is providing support for: clinical monitoring and associated costs; randomisation; statistical analyses and data management.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration