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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
10/09/2004

Recruitment status
Stopped

Registration date
21/09/2004

Overall study status
Stopped

Last Edited
30/06/2011

Condition category
Surgery

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Primary study design
Interventional

Study design
Randomised controlled trial

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