

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/09/2004	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/06/2011	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Parastomal 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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2004

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

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

Not provided at time of registration

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

England

United Kingdom

Study participating centre

Colorectal Surgical Unit

Bradford

United Kingdom

BD9 6RJ

Sponsor information

Organisation

Tissue Science Laboratories plc (UK)

Sponsor details

Victoria House

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Sponsor type

Industry

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

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