ISRCTN79431254 https://doi.org/10.1186/ISRCTN79431254

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr John Griffith

Contact details
Colorectal Surgical Unit
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ
John.Griffith@bradfordhospitals.nhs.uk

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
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 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
Victoria Road
Aldershot
United Kingdom
GU11 1EJ
+ 44 (0) 1252 333002
ccurtis@tissuescience.com

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