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A randomised controlled trial of Permacol® reinforcement of permanent stomas versus standard technique in reduction of parastomal hernia

Submission date 12/07/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 11/08/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 25/09/2013	**Condition category** Digestive System	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RL100

Study information

Scientific Title

Acronym
PROPHECI

Study objectives
Our hypothesis is that reinforcing the stoma trephine with Permacola® when the stoma is being formed is superior to the standard technique without reinforcement in terms of preventing herniation, and the use of Permacol® is associated with less morbidity, infection and pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Huntingdon Research Ethics Committee on 30/05/2006 (reference number: 06 /Q0104/32).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Parastomal herniation

Interventions
We intend to randomise a cohort of patients who are undergoing permanent stoma formation for a variety of elective procedures between collagen mesh reinforcement of the stoma versus no mesh as control.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Permacola®

Primary outcome measure
1. To determine the efficacy of Permacol® in reducing the incidence of parastomal hernia
2. To test whether the use of collagen mesh reinforcement is associated with lower rates of clinical herniation than no reinforcement. This will be evaluated at discharge and one, six, 12, 18 and 24 months post-operatively.

Secondary outcome measures
The secondary objectives of the study will be to determine differences in:
1. The radiological incidence of herniation as detected by Computerised Tomography (CT) scan and correlate this with the primary objective at 12 months
2. Complications associated with the technique used for the reinforcement. These will be evaluated at discharge and one, six, 12, 18 and 24 months post-operatively.
3. The handling characteristics, ease of insertion and suturing of the implant will be evaluated by the surgeon
4. Cost-benefit analysis comparing the cost of the reinforcement technique and the length of stay
5. Quality of life assessed using short-form-36 questionnaire (SF36) version two and EuroQol EQ-5D before and at one, six, 12, 18 and 24 months post-operatively

Overall study start date
01/07/2006

Completion date
01/08/2009

Eligibility

Key inclusion criteria
1. Requirement of an elective permanent stoma due to bowel disease
2. Written informed consent
3. Must be aged 18 -100 years and agree to the randomised procedure
4. If of childbearing potential, must have given a negative pregnancy test

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. If participant is taking part in another clinical study, which directly relates to this study
2. Suffering from an untreated metabolic or systemic illness (e.g. diabetes or rheumatoid arthritis or any immunological disease)
3. A diagnosis of mentally limiting conditions such as Alzheimer's or mental retardation or is unable to understand all study requirements
4. Is allergic to any porcine or collagen products
5. Has any indication of a Methicillin-Resistant Staphylococcus Aureus (MRSA) infection
6. Any indication of abdominal wall sepsis

Date of first enrolment
01/07/2006

Date of final enrolment
01/08/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Tissue Science Laboratories
Hampshire
United Kingdom
GU11 1EJ

Sponsor information

Organisation
Tissue Science Laboratories plc (UK)

Sponsor details
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Sponsor type
Industry

Website
http://www.tissuescience.com/

ROR
https://ror.org/020hbh524

Funder(s)

Funder type
Industry

Funder Name
Tissue Science Laboratories plc (UK)

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