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

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