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# Use of prolene mesh to prevent incisional hernia after elective repair of an abdominal aortic aneurysm

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 30/09/2004 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 30/09/2004 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 02/10/2014 | Circulatory System | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Mr David Mitchell

**Contact details**
Department of Vascular Surgery
Southmean Hospital
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

## Additional identifiers

**Protocol serial number**
N0106133351

## Study information

**Scientific Title**

Mesh abdominal aortic aneurysm (AAA) repair trial: a randomised prospective controlled trial studying the use of prolene mesh in the abdominal wound closure of patients undergoing standard AAA repair

## Study objectives
Current hypothesis as of 13/10/2009:
Incisional hernia is a significant problem following standard open AAA repair, occurring in about 1/3 of patients undergoing this procedure. Placement of a prolene mesh between the posterior rectus sheath/anterior peritoneum and the rectus muscle has been shown in a small feasibility study to be a safe technique for abdominal wound reinforcement during standard open AAA repair and appeared to prevent hernia occurrence. It is the aim of this prospective randomised controlled trial to:
1. Provide robust evidence of differences in hernia rates between standard and mesh closure techniques
2. Compare complication rates between the two groups
3. Give clear indication based on the above evidence as to whether this technique should be used routinely for the closure of all abdominal wounds following standard open AAA repair

Previous hypothesis:
Does the use of the routine placement of prolene mesh into patients undergoing elective abdominal aortic aneurysm repair reduce the number of post-operative incisional hernias?

On 13/10/2009 the sources of funding field was updated. The previous text was 'Gloucestershire R&D Consortium (UK).

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Initial ethics approval was obtained from the Gloucestershire Research Ethics Committee (ref: 04/Q2005/33) and subsequently extended to North Bristol NHS Trust via Frenchay Research Ethics Committee (ref: S105/03). The Gloucestershire REC has now closed and all enquiries are now handled by Frenchay REC, Pembroke Room, Beaufort House, Southmead Hospital, Westbury-on-Trym, Bristol, BS10 5NB. It was fully approved in July 2004.

## Study design
Multicentre randomised non-blinded controlled clinical study

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Abdominal aortic aneurysm

## Interventions
1. Routine mass closure with nylon sutures (standard)
2. Abdominal closure using polypropylene

Added 13/10/2009:
Follow-up at 1, 3, 6, 12, 24 and 36 months post-surgery.

Initial contact details at time of registration:
Mr Jonathan Earnshaw
Gloucester Royal Hospital

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome(s)
Current primary outcome measures as of 13/10/2009:
Presence of incisional hernia

Previous primary outcome measures:
Reduction in post-operative hernia, reduction in number of subsequent hernia repairs

### Key secondary outcome(s))
Added 13/10/2009:
1. Duration of surgery
2. Complication rate
3. Re-operation rate

### Completion date
31/12/2006

## Eligibility

### Key inclusion criteria
Added 13/10/2009:
All patients presenting for open abdominal aortic aneurysm repair

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
Added 13/10/2009:
1. Inability to give written informed consent

2. Condition predisposing to infection, including immuno-compromise or faecal contamination /soiling but not including diabetes mellitus

**Date of first enrolment**
03/10/2003

**Date of final enrolment**
31/12/2006

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**Department of Vascular Surgery**
Bristol
United Kingdom
BS10 5NB

# Sponsor information

**Organisation**
Department of Health

# Funder(s)

**Funder type**
Government

**Funder Name**
Gloucestershire Hospitals NHS Foundation Trust (UK)

**Funder Name**
North Bristol NHS Trust (UK)

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/10/2010 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |