

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

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 02/10/2014	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**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  
Southmead 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?
<a href="#">Results article</a>	results	01/10/2010		Yes	No