ISRCTN28485581 https://doi.org/10.1186/ISRCTN28485581

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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
Added 13/10/2009:
1. Duration of surgery
2. Complication rate
3. Re-operation rate

Overall study start date
03/10/2003

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

Age group
Adult

Sex
Both

Target number of participants
100 patients undergoing elective aortic aneurysm repair

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
England

United Kingdom

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

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Gloucestershire Hospitals NHS Foundation Trust (UK)

Funder Name
North Bristol NHS Trust (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2010		Yes	No