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Does the choice of suture material affect outcome in the formulation of an intestinal stoma?

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 14/03/2014	**Condition category** Surgery	

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
N0283122687

Study information

Scientific Title

Study objectives
Is there any difference in terms of complication rate or ease of use with three of the commonly used sutures for stoma formation?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Laparotomy

Interventions
This is a single centre prospective randomized controlled trial comparing the complication rates of vicryl, polydioxanone suture (PDS) or biosyn.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Primary outcome measures are numbers of complications.

Secondary outcome measures
Length of hospital stay and time to independence in managing the stoma.

Overall study start date
16/10/2002

Completion date
30/10/2006

Eligibility

Key inclusion criteria
90 consenting patients due to undergo a laparotomy will be prospectively randomized into three groups.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
90

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
16/10/2002

Date of final enrolment
30/10/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Worthing & Southlands Hospitals NHS Trust
Worthing, West Sussex
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BN11 2DH

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
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Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Sussex NHS Research Consortium (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