

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
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 14/03/2014	Condition category Surgery	☐ Individual participant data
		☐ 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

Primary outcome measures are numbers of complications.

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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**

United Kingdom

England

Study participating centre

Worthing & Southlands Hospitals NHS Trust

Worthing, West Sussex

United Kingdom

BN11 2DH

Sponsor information**Organisation**

Department of Health (UK)

Funder(s)**Funder type**

Government

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration