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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr William Woods

Contact details

Worthing & Southlands Hospitals NHS Trust Worthing Hospital Lyndhurst Road Worthing, West Sussex United Kingdom BN11 2DH

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 United Kingdom BN11 2DH

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

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