A comparison of patient satisfaction and complications following keyhole surgery wounds closed with tissue glue or stitches

Submission date	Recruitment status	Prospectively registered
27/11/2009	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
15/12/2009	Completed	Results
Last Edited	Condition category	Individual participant data
20/05/2016	Surgery	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

06/wmw01/55

Study information

Scientific Title

Patient satisfaction and complications following laparoscopic wound closure with 2-octylcyanoacrylate or vicryl: a single blind randomised controlled trial

Study objectives

Closure of laparoscopic wounds with tissue adhesives is associated with higher patient satisfaction and lower complication rates than with conventional suturing.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Dyfed Powys Research Ethics Committee approved on the 3rd January 2007 (ref: 06/wmw01/55)

Study design

Single blind randomised controlled trial

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

Laparoscopic general surgery

Interventions

Intervention: Laparoscopic wound closure with 2-cyanoacrylate tissue adhesive Control: Laparoscopic wound closure with subcuticular stitches

Total follow up was six weeks.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome measure

Patient satisfaction in terms of wound appearance and wound closure technique. Measured at six weeks post-operatively.

Secondary outcome measures

- 1. Wound closure time, measured at the time of operation
- 2. Wound complications (dehisence, infection, resuturing), measured at six weeks postoperatively
- 3. Wound pain, measured at six weeks post-operatively
- 4. Antibiotic usage, measured at the time of operation
- 5. Unscheduled medical review, measured at six weeks post-operatively

Overall study start date

01/02/2007

Completion date

01/02/2009

Eligibility

Key inclusion criteria

- 1. All adults (aged 18 years and over), both males and females
- 2. Elective, general surgical, laparoscopic patients

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

300

Key exclusion criteria

- 1. Known 2-octylcyanoacrylate hypersensitivity
- 2. Conversion to open procedure

Date of first enrolment

01/02/2007

Date of final enrolment

01/02/2009

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre
Department of Gastrointestinal Surgery
Swansea
United Kingdom
SA2 8QA

Sponsor information

Organisation

Carmarthenshire NHS Trust (UK)

Sponsor details

Research and Development Office
Room 8, Mynydd Mawr Hospital
Upper Tumble
Llanelli
Wales
United Kingdom
SA14 6BU
+44 (0)1269 833397
ingaret.eden@carmarthen.wales.nhs.uk

Sponsor type

Hospital/treatment centre

Website

http://www.wales.nhs.uk/sites3/home.cfm?orgid=45

Funder(s)

Funder type

Government

Funder Name

Carmarthenshire NHS Trust (UK) - Research and Development Office (now known as Hywel Dda NHS Trust)

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration