

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

Submission date 27/11/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 15/12/2009	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 20/05/2016	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
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

1. Wound closure time, measured at the time of operation
2. Wound complications (dehiscence, infection, resuturing), measured at six weeks post-operatively
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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration