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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

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 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

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
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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 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