

Transvaginal laparoscopic cholecystectomy versus standard laparoscopic cholecystectomy

Submission date 10/10/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/12/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 14/05/2013	Condition category Digestive System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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
N/A

Study information

Scientific Title

Acronym
TV-CCE

Study objectives

H0: There is no reduction of pain (NRS ≥ 1) while resting or while coughing on the day of operation, on the first postoperative or on the second postoperative day with a transvaginal assisted cholecystectomy compared to a laparoscopic cholecystectomy.

H1: There is a reduction of pain (NRS ≥ 1) while resting or while coughing on the day of operation, on the first postoperative or on the second postoperative day with a transvaginal assisted cholecystectomy compared to a laparoscopic cholecystectomy.

Please note that as of 14/05/2013, the anticipated end date for this trial was updated from 01/06/2010 to 12/06/2012

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) approved in April 2008 (ref: EA1/035/08).

Study design

Prospective randomised controlled multicentre trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cholecystolithiasis

Interventions

1. Transvaginal cholecystectomy
2. Laparoscopic cholecystectomy

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Reduction of pain, assessed with a numeric rating scale.

All outcomes will be assessed on the 7th and 28th postoperative day and 1 year after surgery.

Key secondary outcome(s)

1. Wound infections
2. Trokar herniation
3. Morbidity
4. Mortality

5. Complications
6. Fatigue
7. Costs
8. Quality of life, assessed by a tool developed by Eypasch et al (1995) and SF-36 Health Survey
9. Long-term outcome

All outcomes will be assessed on the 7th and 28th postoperative day and 1 year after surgery.

Completion date

12/06/2012

Eligibility

Key inclusion criteria

1. Female
2. Full age (18 years or older)
3. Symptomatic cholecystolithiasis

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

1. Male
2. <18 years
3. Patients desire for transvaginal/laparoscopic operation
4. Multiple adhesions
5. emergency
6. Acute cholecystitis
7. Choledocholithiasis
8. Malignoma
9. Acute vaginal infection
10. Gynaecological disease
11. Gravidity
12. Endometriosis
13. American Society of Anesthesiologists (ASA) IV
14. Liver disease (Child Pugh Criteria A, B, C)

Date of first enrolment

01/06/2008

Date of final enrolment

12/06/2012

Locations

Countries of recruitment

Germany

Study participating centre

Sana Klinikum Berlin Lichtenberg

Berlin

Germany

10365

Sponsor information

Organisation

Sana Hospital Lichtenberg (Sana Klinikum Lichtenberg) (Germany)

ROR

<https://ror.org/0071tdq26>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Sana Hospital Lichtenberg (Sana Klinikum Lichtenberg) (Germany)

Funder Name

Olympus (Japan)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration