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Transvaginal laparoscopic cholecystectomy versus standard laparoscopic cholecystectomy

Submission date	Recruitment status	[ ] Prospectively registered
10/10/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/12/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/05/2013	Digestive System	[ ] 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
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

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
Cholecystolithiasis

Interventions
1. Transvaginal cholecystectomy
2. Laparoscopic cholecystectomy

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
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.

Secondary outcome measures
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.

Overall study start date
01/06/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
88

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)

Sponsor details
Fanninger Str 32
Berlin
Germany
10365

Sponsor type

Hospital/treatment centre

Website
http://www.khl-berlin.de

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

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