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Comparative study of the effectiveness of training on a Simbionix simulator and training on a box trainer simulator when learning laparoscopic cholecystectomy

Submission date 14/03/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 19/04/2006	**Overall study status** Completed	
Last Edited 14/08/2008	**Condition category** Other	

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

Study objectives
Superiority of education on the Simbionix simulator compared to education on the box trainer simulator

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval not required, study does not deal with humans, human tissues or living animals

Study design
StratIfied randomised, blinded trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Laparoscopic training techniques

Interventions
Different training:
Group 1: Training on Simbionix simulator
Group 2: Training on box trainer simulator
Group 3: Control group: no training

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Proof of superiority of Simbionix-simulator-training compared to training on a box-trainer-simulator and proof of the effectiveness of both training methods compared to no training

Secondary outcome measures
Evaluation of the acceptance of training on the Simbionix-simulator by the participating surgical residents.

Overall study start date
20/04/2006

Completion date
31/12/2006

Eligibility

Key inclusion criteria
Voluntary participation from the surgical residents (from hospitals in northern Germany)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
78

Key exclusion criteria
1. Number of laparoscopic operations >10
2. Number of laparoscopic cholecystectomies >5
3. Previous participation in a laparoscopic training course
4. Experience of practicing on Simbionix simulators or box trainers

Date of first enrolment
20/04/2006

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Germany

Study participating centre
European Surgical Institute
Norderstedt
Germany
22851

Sponsor information

Organisation
Simbionix (Israel)

Sponsor details
6 Hamelacha Street
Lod
Israel
71520

Sponsor type
Industry

Website
http://www.simbionix.com

ROR
https://ror.org/03xg8x064

Funder(s)

Funder type
Industry

Funder Name
European Surgical Institute (Germany)

Funder Name
Simbionix (Israel)

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