

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

<b>Submission date</b> 14/03/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/04/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 14/08/2008	<b>Condition category</b> Other	<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

### Contact name

Mr Thomas Buerger

### Contact details

European Surgical Institute  
Hummelsbuetteler Steindamm 71  
Norderstedt  
Germany  
22851

## 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