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# Simulation can improve patients' security in endoscopic procedures

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 01/02/2016 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 02/02/2016 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 02/02/2016 | Surgery | [ ] Record updated in last year |

## Plain English summary of protocol

Background and study aims
Appropriate sedation is a crucial part for a successful gastrointestinal (GI) procedure (surgery on the digestive system). Sedation for GI procedures is mostly done by the gastroenterologist in charge. However, many of them do not have the training required to prevent possible complications or side effects. Simulation has proven to be an excellent teaching tool for teaching both technical and non-technical skills, communication, crisis management and improving patient safety.
The aim of this study was to test the impact of anesthesiologist (doctors that administer local or general anesthetic during surgery) led simulation sessions on sedation for GI procedures done by non-anesthesiologists.

Who can participate?
Medical doctors aged between 25-65 and undergoing endoscopic procedures.

What does the study involve?
Each participant is observed while they perform 15 consecutive endoscopic procedures. They then attend a simulation training course about sedation for endoscopic procedures. Finally, they are all observed again while they perform another 15 endoscopic procedures.

What are the possible benefits and risks of participating?
The participants in this study may improve their knowledge and skills in sedating patients when performing endoscopic procedures. There are no risks associated with taking part in the study.

Where is the study run from?
Catholic University of Chile, Christus Clinical Hospital (Chile)

When is the study starting and how long is it expected to run for?
April 2013 to October 2015

Who is funding the study?
National Commission for Scientific and Technological Research (Chile)

Who is the main contact?
Mr Alejandro Delfino

# Contact information

### Type(s)
Scientific


### Contact name
Mr Alejandro Delfino

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# Additional identifiers

# Study information

### Scientific Title
The use of simulation to improve patients' security under sedation in endoscopic procedures

### Study objectives
The introduction of a practical teaching course about sedation based on simulation can improve the sedation's quality and the patients´ security.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Ethics committee at Catholic University of Chile (Pontificia Universidad Catolica de Chile), 06/08/2013

### Primary study design
Interventional

### Study design
Prospective interventional single-centre non randomised clinical trial

### Study type(s)
Prevention

### Health condition(s) or problem(s) studied
Sedation

### Interventions
A group of 10 endoscopists were prospectively observed during 15 consecutive endoscopic procedures. After that, all subjects attended a simulation teaching course about sedation for endoscopic procedures. Finally, the same subjects were prospectively observed during 15 endoscopic procedures.

The simulation teaching course:
Three high-fidelity simulation cases (upper airway obstruction, agitation and hemodynamic instability) were designed according to the essential elements of the checklist. Each session consisted of a detailed prebriefing, followed by one simulation case. After each scenario, a trained instructor guided a debriefing session focused on technical and nontechnical skills performance.

Three months after the intervention the gastroenterologists' sedation performance was re-evaluated with the use of the checklist. Differences before/after the intervention was calculated using the McNemar's test. A $p \leq 0.05$ was considered significant.

### Intervention Type
Behavioural

### Primary outcome(s)
1. Patients sedations' quality under endoscopic procedures. To measure this an specific checklist was developed. This instrument was used pre and three month after the intervention
2. Knowledge about sedation: this was measured pre and three month after the intervention using a specific multiple choice question test

### Key secondary outcome(s)
Serious adverse events: a comparison was performed between the institution historic register of adverse events between January 2010 and December 2013 and the prospective register from the studied population during nine month after the intervention.

### Completion date
12/10/2015

## Eligibility

### Key inclusion criteria
1. Medical doctors who perform endoscopic procedures
2. Aged 25 to 65 years
3. Agreed to participate in the simulation sessions

### Participant type(s)
Health professional

### Healthy volunteers allowed
No

### Age group
Adult

**Sex**
All

**Key exclusion criteria**
Participants that don't fulfill the inclusion criteria

**Date of first enrolment**
05/04/2013

**Date of final enrolment**
12/04/2015

## Locations

**Countries of recruitment**
Chile

**Study participating centre**
**Catholic University of Chile (Pontificia Universidad Catolica de Chile)**
Christus Clinical Hospital
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## Sponsor information

**Organisation**
Catholic University of Chile (Pontificia Universidad Catolica de Chile)

**ROR**
https://ror.org/04teye511

## Funder(s)

**Funder type**
Government

**Funder Name**
Comisión Nacional de Investigación Científica y Tecnológica

**Alternative Name(s)**

National Commission for Scientific and Technological Research, CONICYT

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
Chile

# Results and Publications

## Individual participant data (IPD) sharing plan

**IPD sharing plan summary**
Available on request