

Simulation can improve patients' security in endoscopic procedures

Submission date 01/02/2016	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 02/02/2016	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 02/02/2016	Condition category Surgery	☐ Individual participant data ☐ 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
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Additional identifiers

Protocol serial number
N/A

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

Study design
Prospective interventional single-centre non randomised clinical trial

Primary study design
Interventional

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

Marcoleta 367

Santiago

Chile

8330024

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes