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

ORCID ID http://orcid.org/0000-0002-0659-7130

Contact details Marcoleta 367 Santiago Chile 8330024

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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 Univer

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

Secondary study design

Non randomised study

Study setting(s) Hospital

Study type(s) Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 reevaluated with the use of the checklist. Differences before/after the intervention was calculated using the McNemar's test. A $p \le 0.05$ was considered significant.

Intervention Type

Behavioural

Primary outcome measure

 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
Knowledge about sedation: this was measured pre and three month after the intervention using a specific multiple choice question test

Secondary outcome measures

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.

Overall study start date

05/04/2013

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

Age group Adult

Sex Both

Target number of participants 10 participants

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)

Sponsor details

Marcoleta 367 Santiago Chile 8330024

Sponsor type University/education

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

Publication and dissemination plan

During the present year I will submit the original paper to one journal dedicated preferentially to endoscopic procedures.

Intention to publish date 31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request