ISRCTN11922400 https://doi.org/10.1186/ISRCTN11922400

Pre-induction checklist and human factors in airway management

Submission date	Recruitment status	[_] Prospectively registered
09/08/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/08/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/03/2022	Surgery	

Plain English summary of protocol

Background and study aims
Failure during airway management can result in a patient's life-long impairment or death. Human factors contribute to errors. Cognitive aids influence human factors. Checklists are a well-known cognitive aid. In May 2016, the Department of Anaesthesiology and Pain Medicine, University of Bern developed an electronically pre-induction checklist consisting of four items with the aim to improve human factors and raise patient safety during airway management. This audit aims to investigate the compliance with the pre-induction checklist over a retrospective 5- year period.

Who can participate?
Data is analysed from all patients of all ages undergoing procedures with airway management in general and combined (general and regional) anaesthesia performed by the Department of Anaesthesiology and Pain Medicine from June 2016 to May 2021.

What does the study involve?
Patients data is compared from before and after the introduction of a departmental pre-induction checklist in May 2016 and a strong recommendation to use it before the start of every general anaesthesia.

What are the possible benefits and risks of participating?
This audit aims to bridge the gap of knowledge with the compliance of cognitive aids and can potentially identify weaknesses with the aim of further improvement.

Where is the study run from?
Bern University Hospital, Inselspital Bern (Switzerland)

When is the study starting and how long is it expected to run for?
May 2016 to August 2021

Who is funding the study?
Bern University Hospital, Inselspital Bern (Switzerland)

Who is the main contact?
Dr Alexander Fuchs
alexander.fuchs@insel.ch

Contact information

Type(s)
Scientific

Contact name
Dr Alexander Fuchs

ORCID ID
https://orcid.org/0000-0001-7188-1683

Contact details
Freiburgstrasse
Bern
Switzerland
3010
+41 (0)31 632 39 65
alexander.fuchs@insel.ch

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
PILOT-1

Study information

Scientific Title
Implementation of an anaesthesia pre-induction checklist to improve patients' safety during airway management – a retrospective single-centre 5-year cohort analysis (Pre-Induction checkList cOmpliance audiT [PILOT])

Acronym
PILOT

Study objectives

Retrospective observational study 5 years after the implementation of a departmental electronically pre-induction checklist as a cognitive aid to improve patient's safety during airway management. This audit aims to analyse the compliance with the departmental pre-induction checklist over five years.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/04/2021, Gesundheits- und Fürsorgedirektion des Kantons Bern, Kantonale Ethikkomission für die Forschung Bern (Ethics Committee of the Canton of Bern, Murtenstrasse 31, 3010 Bern, Switzerland; +41 (0)31 633 7070; info.kek.kapa@gef.be.ch), ref: Req-2021-00428

Study design
Retrospective single-centre observational cohort study

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
All patients with procedures in general or combined general/regional anaesthesia provided by the Department of Anaesthesiology and Pain Medicine, University Hospital Bern

Interventions
Introduction of a departmental electronically pre-induction checklist in May 2016, and a strong recommendation to use it before the start of every general anaesthesia

Categorical variables will be reported as absolute (n) and relative frequencies (%), continuous variables using mean (SD) or median (IQR).
The researchers will perform a t-test for continuous variables or one-way ANOVA for parametric data, Mann–Whitney or Kruskal–Wallis tests for nonparametric data, and Chi-squared tests or Fisher’s exact tests for categorical variables. Univariate and multivariate logistic regression will be performed (type of surgery, time of the day and emergency category on completely performed checklist). The significance level of probability will be defined as ≤0.05.

Intervention Type
Behavioural

Primary outcome(s)
Frequency of completely performed pre-induction checklist, sourced out of the departmental electronically anaesthesia information system at baseline

Key secondary outcome(s))
Sourced out of the departmental electronically anaesthesia information system at baseline:
1. Urgency of the procedure: emergency procedure (immediate or within 12 h) vs non-emergency procedure (within 24 h or elective)
2. Area of anaesthesia induction: operating room vs non-operating room

3. Surgical type of procedure
4. Time of anaesthesia induction, standard working hours (7:00 h-16:59 h) vs. on-call hours (reduced personal, 17:00 h-6:59 h)
5. Patients' basic demography (age, weight, height and ASA physical status)

Completion date
31/08/2021

Eligibility

Key inclusion criteria
All procedures in general anaesthesia or combined general with regional anaesthesia

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Total final enrolment
120000

Key exclusion criteria
Procedures solely performed in regional anaesthesia or in sedation

Date of first enrolment
01/06/2016

Date of final enrolment
31/05/2021

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital Bern, Inselspital
Department of Anaesthesiology and Pain Medicine
Freiburgstrasse

Bern
Switzerland
3010

Sponsor information

Organisation
University Hospital of Bern

ROR
https://ror.org/01q9sj412

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Inselspital, Universitätsspital Bern

Alternative Name(s)
Inselspital, Bern University Hospital, Inselspital, Bern University Hospital, University Hospital of Bern, Universitätsspital Bern, Inselspital, Hôpital universitaire de Berne

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request from Dr Alexander Fuchs (alexander.fuchs@insel.ch) for other researchers or non-profit organizations after approval and agreement of the responsible cantonal ethics committee. Quantitative data is expected to be available from

January 2022, for a period of 10 years. All researchers will comply with the Data Protection Act and the Swiss Law for Human Research. All data will be destroyed 10 years after the end of the project.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/03/2022	21/03/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes