Supplementary information

Protocol version 6

Issue date: Dec 2021

Protocol amendment number: 04

Authors: BG, CB, LS, SDK

Revision chronology:

2019-Sept-25 Original

2021-Apr-04 Amendment 1

2021-Aug-11 Amendment 2

2021-Sept-07 Amendment 3

2021-Dec-05 Amendment 4

Primary reason for amendment:

1) Before start of recruitment: newly published, validated translation of QoR-15 in French, further secondary endpoints, randomisation using variable block sizes

2) After start of recruitment: Additional study centre

3) After start of recruitment: Additional methods for excluding pregnancy

4) After start of recruitment: change in PI in one centre which has not yet started the recruitment

Primary registry and trial identifying number	ClinicalTrials.gov NCT04105660
Date of registration in primary registry	25 Sept, 2021
Secondary identifying numbers	2019-00132
Source(s) of monetary or material support	Swiss Life Jubiläumsstiftung Foundation for Research and Education, University Basel Foundation for Research and Education in Anaesthesia, Basel
Primary sponsor	University Hospital, Basel, Switzerland

	Prof. Dr. Luzius Steiner, MD PhD Chairman Clinic for Anaesthesiology, Intermediate Care, Prehospital Emergency Medicine and Pain Therapy
Secondary sponsor(s)	Kantosspital Graubünden, Chur, Switzerland
Contact for public queries	CB, SDK, LS
Contact for scientific queries	CB, SDK, LS
Public title	Electroencephalogram (EEG) in General Anaesthesia - More Than Only a Bispectral Index (BIS)
Scientific title	*Multicentre, double-blind, randomised controlled trial comparing propofol anaesthesia guided by bispectral index monitoring and frontal EEG wave analysis compared to standard monitoring in laparoscopic surgery*
Countries of recruitment	Switzerland
Health condition(s) or problem(s) studied	Quality of recovery after general anaesthesia
Intervention(s)	Training for reading EEG curves during anaesthesia
	Standard monitoring including clinical parameters and BIS index
Key inclusion and exclusion criteria	Ages eligible for study: ≥18 years Sexes eligible for study: both Accepts healthy volunteers: no
	Inclusion criteria: adult patient (≥ 18 years), planned in-hospital laparoscopic surgery
	Exclusion criteria: same-day surgery, language barrier, patients under 18 years of age, pregnancy, allergy to propofol, administration of hypnotics other than propofol, such as ketamine or midazolam preoperatively or intraoperatively, known brain pathology, such as seizure disorders, dementia, cerebrovascular disease or brain death
Study type	Interventional
	Allocation: randomized intervention
	Primary purpose: better quality of recovery after general anaesthesia
	Phase – not applicable
Date of first enrolment	June 2021
Target sample size	200
Recruitment status	Recruiting

Primary outcome(s)	Quality of recovery (QoR): QoR-15 scale 24 hours after surgery
Key secondary outcomes	Propofol consumption, Time spent in postanaesthesia care unit (PACU), Time to extubation