Appendix I - Anesthetic Data Collection Form

HFMG vs conventional O_2 RCT

DAY OF PROCEDURE ANAE DATA SHEET page 1 **Participant No.** | | | __ __STICKER HERE __

Inclusion criteria: Any low-risk patient with an upper endo proc expected to last≤20 min (excluded Mallampati>3, ASA>3, BMI>35, O_2 dependent)

Pre-procedure data

A.	Procedure **date** (d/m/y):	/ /
B.	Comorbidities:	1 HTN ☐ 2 DM ☐ 3 Dyslipidaemia ☐ 4 COPD/asthma ☐ 5 Current smoker ☐ 6 Previous smoker ☐ Stopped _____ago 7 CCF ☐ 8 IHD ☐ 9 Arrhythmia ☐ 10 CKD ☐ 11 Previous TIA/stroke ☐ 12 Cirrhosis (etiology): ☐ _____ 13 Post liver transplant ☐ 14 Other (specify) ☐ _____
C.	Anaesthetist **consultant**:	Dr
D.	Anaesthetist **fellow/registrar (if present)**:	
E.	**Mallampati score**	1 ☐ 2 ☐ 3 ☐
F.	**ASA grade**	I ☐ II ☐ III ☐
G.	**Baseline O_2 sat (room air)**	%
H.	**Height**	centimetres
I.	**Weight**	kg
J.	**RCT arm**	1 Std cannula at 2L/min ☐ 2 HFMG at 20L/min ☐
K.	**Sedation started**	H M
L.	**Sedation stopped**	H M
M.	**Minimum O2 sat during sedation**	%

Post-procedure data

P.	**PROPOFOL** total dose	mg
Q.	**OPIOID** total dose	Alfentanil _____mcg Fentanyl _____mcg
R.	**Midazolam** total dose	mg
S.	**Other medication** used (name and dose please)	
M.	**Any episodes of desaturation, sedation-related adverse events, complications or unusual post-op order/procedure?**	0 No (**end the form here**) ☐ 1 Yes (**continue up to p.2**) ☐ 1a Desaturation episodes but no change in management ☐ 1b Desaturation episodes with change in management ☐ 1c Complication/unusual procedure necessary ☐
N.	**Types of maneuvers necessary for desaturation**	1 Chin lift/jaw thrust ☐ 2 Increase O2 flow ☐ Specify max flow used _____ 3 Change to HFNC arm ☐ 4 Intubation ☐ 5 Procedure interrupted ☐ 6 Drug reversal agents ☐ 7 Other (specify) ☐: _____
O.	**Sedation-related adverse events**	1 Nausea/vomit ☐ 2 Myoclonus ☐ 3 Paradoxical response ☐ 4 Recovery agitation ☐ 5 Recovery delay ☐ 6 Airway obstruction ☐ 7 Bradycardia ☐ 8 Tachycardia ☐ 9 Hypotension ☐ 10 Seizure ☐ 11 Cardiovascular collapse ☐ 12 Cardiac arrest ☐ 13 Other (specify) ☐: _____
U.	**Overnight admission required post-procedure?**	0 No ☐ 1 PRAE ☐ 2 SRAE (specify) ☐ _____ 3 Due to comorbidities ☐ 4 Other reason (specify)☐ _____

PAGE 1 of 2

Desaturation Chart

Desaturation level	# Episodes that lasted <1 minute	# Episodes that lasted ≥1 minute but <5 minutes	# Episodes that lasted ≥5 minutes
Very mild (≤94%)			
Mild (≤92%)			
Moderate (≤90%)			
Severe (≤75%)			

PAGE 2 of 2

Appendix II - Procedure Data Collection Form

HFMG vs conventional O_2 RCT

DAY OF PROCEDURE ENDO DATA SHEET **Participant No.** ____ __ __STICKER HERE __

Inclusion criteria: Any low-risk patient with an upper endo proc expected to last≤20 min (excluded Mallampati>3, ASA>3, BMI>35, O_2 dependent)

Pre-procedure data

A.	Procedure **date** (d/m/y):	/ /
B.	Procedure **type**:	1 Gastroscopy ☐ 2 EUS ☐ 3 ERCP ☐ 4 Enteroscopy ☐ 5 Other (specify) ☐ _____
C.	Endoscopy **consultant**:	1 Rhys ☐ 2 Marios ☐ 3 Sujie ☐ 4 Other (specify) ☐ _____
D.	Endoscopy **fellow/registrar**:	1 Leo ☐ 2 Anton ☐ 3 Kim ☐ 4 Other (specify) ☐ _____
E.	**Main indication** for performing the scope (choose one option only)	**1 Diagnostic (specify) ☐** 1a IDA/bleeding ☐ 1b BO surveillance ☐ 1c Abnormal imaging ☐ 1d BDS/GBS dx ☐ 1e Panc CA screen ☐ 1f Other (specify) ☐ ___ _____ **2 Therapeutic (specify) ☐** 2a Luminal/BD dilation ☐ 2b Endo resection ☐ 2c RFA ☐ 2d APC ☐ 2e GTT ☐ 2f EUS drainage ☐ 2g Spyglass+EHL ☐ 2h BDS treatment ☐ 2i BD/PD stent exchange ☐ 2j Luminal stent placement ☐ 2k Other (specify) ☐ _____
F.	**Time of scope** **IN** **OUT**	H M H M

Post-procedure data

G.	**Any complications or unusual post-op order/procedure?**	0 No **(end the form here)** ☐ 1 Yes **(continue the form)** ☐
H.	**If SRAE**, did it affect the procedure?	0 No ☐ 1 Pause for a few minutes (scope not withdrawn) ☐ 2 Scope withdrawn early (procedure finished) ☐ 2 Scope withdrawn and re-inserted (procedure finished) ☐ 2 Scope withdrawn early (procedure not finished) ☐ 3 Other ☐ _____
I.	Significant **bleeding <u>during procedure</u>** requiring treatment:	0 None ☐ 1 Clip(s) ☐ 2 Adrenaline injection ☐ 3 Gold probe/Coagrasper ☐ 4 STSC ☐ 5 Other ☐_____
J.	**Bleeding control**:	0 Not applicable ☐ 1 Controlled and placed prophylactic clip ☐ 2 Controlled and no further treatment required ☐ 3 Bleeding uncontrolled ☐ If so, outcome: _____
K.	**Perforation** noted during procedure	0 No ☐ 1 Uncertain/Prophylactic clip ☐ 2 Yes ☐
L.	**Treatment of perforation**	0 Not applicable or None ☐ 1 Clips ☐ 2 Laparoscopic Surgery ☐ 3 Open Surgery ☐
M.	**Significant pain** after procedure **requiring admission**	0 No ☐ 1 Yes ☐
N.	**Overnight admission required post-procedure?**	0 No ☐ 1 Social reasons ☐ 2 Co-morbidities ☐ 3 Pain ☐ 4 Bleeding ☐ 5 Fever ☐ 6 Perforation ☐ 7 Large lesion (preventive) ☐ 8 Post-resection syndrome ☐ 9 SRAE ☐ 10 Other reason (specify) ☐

Study Name: High-flow mouthguard versus conventional oxygen therapy for short, low-sedation-risk endoscopic procedures: a randomised single-blinded trial
Protocol Number: 63130
Version & date: version **1.2**, dated **6th of November 2020**

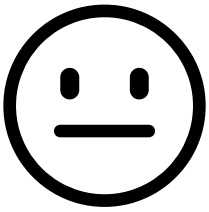
Appendix III - Patient Reported Symptoms Form

Participant No. ☐

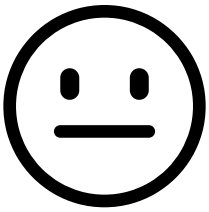
Symptoms visual questionnaire – HFMG vs COT RCT

Please tick the box more closely related to how you are feeling right now:

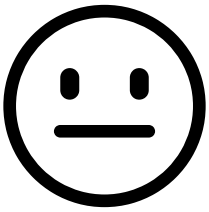
Overall comfort after the endoscopic procedure

				
Very uncomfortable	Uncomfortable	Not comfortable nor uncomfortable	Comfortable	Very comfortable

Abdominal pain

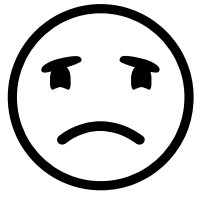
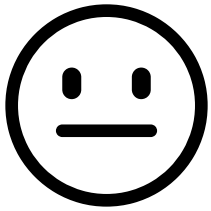
				
Unbearable	Severe	Moderate	Mild	Not at all

Stomach bloating

				
Unbearable	Severe	Moderate	Mild	Not at all

Participant No. [ ]

Nose, mouth or throat DRYNESS

				
Unbearable	Severe	Moderate	Mild	Not at all

Nose, mouth or throat PAIN

				
Unbearable	Severe	Moderate	Mild	Not at all

Headache

				
Unbearable	Severe	Moderate	Mild	Not at all

Appendix IV - Oxyguard study protocol v1.1

PROTOCOL

High-flow mouthguard versus conventional oxygen therapy for short, low-sedation-risk endoscopic procedures: a randomised single-blinded trial

Protocol Number: ND 63130/2020
Version: 1.1
Date: 30/04/2020

Author/s:
Leonardo Zorron Cheng Tao Pu/Sujievvan Chandran/Philip Peyton/Rhys Vaughan/Marios Efthymiou/Anton Rajadurai

Sponsor/s:
Austin Health

Statement of Compliance

This document is a protocol for a research project. This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

TABLE OF CONTENTS

CONTENTS

STUDY SYNOPSIS

Title:	High-flow mouthguard versus conventional oxygen therapy for short, low-sedation-risk endoscopic procedures: a randomised single-blinded trial
Short Title:	HFMG vs COT for short endoscopic procedures
Design:	Randomised clinical trial
Study Centres:	Austin Health
Hospital:	Austin Hospital and Heidelberg Repatriation Hospital
Study Question:	Is high-flow mouthguard a better oxygen delivery method than conventional nasal cannula during short and low-sedation-risk endoscopic procedures?
Study Objectives:	To evaluate the impact of different oxygen delivery methods in clinical outcomes for patients submitted to short and low-sedation-risk endoscopic procedures
Primary Objectives:	Comparison of moderate oxygen desaturation rates (<90%) between the two groups.
Secondary Objectives	Comparison of variable oxygen desaturation rates (e.g. 94%, 92%) between the two groups. Demographics (e.g. gender, age). Comparison of symptoms post-procedure, procedure- and sedation-related adverse events.
Inclusion Criteria:	• Patients referred for upper gastrointestinal endoscopic procedures predicted to last less or equal to 20 minutes (e.g. diagnostic gastroscopies) • Age > 18 years • Ability to give informed consent
Exclusion Criteria:	• Pregnancy • Supplementary O2 dependency • Emergency procedures • Deemed by performing endoscopist as long (>20 minutes) procedure before randomisation

	• Patients with high risk for sedation-related adverse event • Capsule endoscopy procedure
Number of Planned Subjects:	300 (150 each arm)
Investigational product:	Oxyguard and standard nasal cannula (both already standard of care, chosen by the anaesthetist based on subjective criteria)
Safety considerations:	NA (devices already in use at Austin Health)
Statistical Methods:	Randomised clinical trial. Mean ± standard deviation or median (25th and 75th percentile) for continuous data, and as frequency and percentages for categorical data. Statistical analyses will be performed with SPSS statistical software (IBM Corp. 2020. IBM SPSS Statistics, Version 26.0. Armonk, NY).
Subgroups:	High-flow mouthguard and conventional oxygen therapy

1. GLOSSARY OF ABBREVIATIONS & TERMS

Abbreviation	Description (using lay language)
ASA	American Society of Anesthesiologists
SNC	Standard nasal cannula
COT	Conventional oxygen therapy
HFNC	High-flow nasal cannula
HFMG	High-flow mouthguard
PRAE	Procedure-related adverse events
SRAE	Sedation-related adverse events

2. STUDY SITES

a. STUDY LOCATION/S

Site	Address	Contact Person	Phone	Email
Austin Hospital	145 Studley Rd, Heidelberg VIC 3084	Leonardo Zorron Cheng Tao Pu	0433 930 442	leo.zorronchengtaopu@austin.org.au
Heidelberg Repatriation Hospital	300 Waterdale Rd, Heidelberg Heights VIC 3081	Leonardo Zorron Cheng Tao Pu	0433 930 442	leo.zorronchengtaopu@austin.org.au

3. INTRODUCTION/BACKGROUND INFORMATION

a. LAY SUMMARY

Although we know that the use of supplemental oxygen during endoscopic procedures such as gastroscopies is beneficial, various devices and flows can be used. It is still unclear which are the best devices for endoscopic procedures with low sedation risks. This research project is testing which of two oxygen devices with different oxygen flows work better during short endoscopic procedures: a standard nasal cannula at 2L/min or a high-flow mouthguard at 20L/min.

For this study, all patients with low risk for sedation-related complications that will be submitted to long endoscopic procedures (expected to last less or equal to 20 minutes) are being invited to participate. Patients with low risk for sedation are defined through objective technical aspects such as obstructive sleep apnoea and body mass index.

In addition to coming for the scheduled endoscopic procedure and filling out a short 'symptoms visual questionnaire' after the procedure is done, no other actions will be asked from the participant. Information from the procedure and the medical records will be collected, but other than the oxygen delivery method, nothing out of the ordinary will be measured or done during the endoscopic procedure.

b. INTRODUCTION

Endoscopic procedures are becoming more and more common either as diagnostic or as therapeutic procedures. Although advances in medicine are allowing ever growing safety during these procedures, adverse events still happen. These are less common during simple procedures such as gastroscopies but desaturation has been reported to occur in up to 8.4% of ASA I/II patients undergoing gastroscopies (Lin et al. 2019, p. 597). The conventional oxygen therapy (COT) usually consists of using a standard nasal cannula (SNC) at 2L/min for low-risk cases, whereas a sensible choice for high-risk patients is general anaesthesia with endotracheal intubation or high-flow nasal device, especially for lengthy/complex endoscopic procedures (Smith et al. 2019, pp. 856-861; Dimou et al. 2019, p. 3831).

c. BACKGROUND INFORMATION

In the study by Lin et al. (2019, pp. 592-597), this was addressed with the high-flow nasal cannula (HFNC) which eliminated the occurrence of desaturation in their cohort. The HFNC

device though adds an expense to the procedure that might not be necessary. The current mouthguard used in our endoscopies has an integrated oxygen delivery system which potentially allows the delivery of up to 20L/min oxygen flow, what supposedly might be enough to avoid episodes of desaturation. In addition to the potential savings with the device itself, the potential savings with a lower flow (20L/min compared to 60L/min) is not negligible. Hypothetical calculations were performed utilising as prerogatives the cost of HFNC per patient (~AUD 35/procedure) and the cost of medical oxygen (~AUD 0.01/L). Applying these prerogative on the estimated annual number of simple/short endoscopic procedures (~5000) would translate into potential savings close to 200,000 Australian dollars per year.

The study aims to compare the COT with the novel HFMG for the occurrence of desaturation episodes during long endoscopy procedures for low risk patients. The findings of this study can contribute to changes in the standard of care for these procedures, leading to safer/more cost-effective management of these patients.

4. Study Objectives

a. Hypothesis

The use of high-flow mouthguard (HFMG) reduces episodes of desaturation in patients with low sedation risk undergoing short endoscopic procedures.

b. Study Aims

The aim of this study is to compare the use of HFMG (Oxyguard D® at 20L/min) versus COT (SNC at 2L/min) for low-risk patients undergoing elective short (≤20 minutes) endoscopic procedures in an Australian tertiary hospital.

c. Outcome Measures

Primary outcome: Comparison of moderate oxygen desaturation rates (<90%) between the two groups.

Secondary outcomes: Comparison of variable oxygen desaturation rates (e.g. 94%, 92%) between the two groups. Demographics (e.g. gender, age). Comparison of symptoms post-procedure, procedure- and sedation-related adverse events.

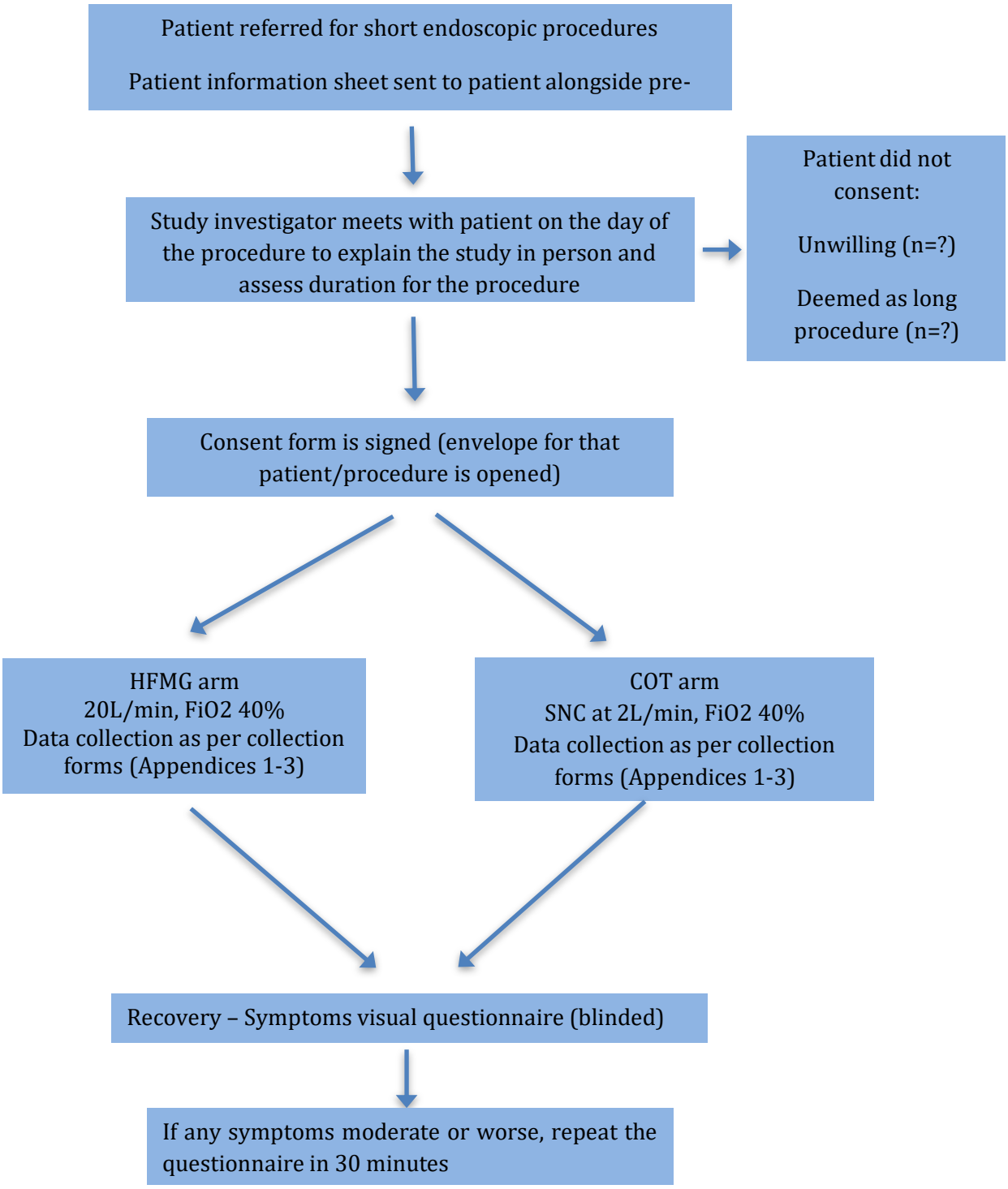
5. Study Design

a. Study Type & Design & Schedule

Randomised controlled trial. This study will be registered at clinicaltrials.gov prior to the enrolment of the first patient.

Sequence of Procedures

Study Flowchart



Description of sequence of procedures

1. Patient is referred to the endoscopy unit for any endoscopy procedure in a list of one of the investigators/co-investigators (as outpatient or inpatient, from Austin or external referral).

2. Assessed by an Endoscopy Unit specialist (either endoscopy registrar, endoscopy fellow, endoscopy consultant or advanced endoscopy nurse coordinator assess the procedure as long or short).

3. If deemed as potentially short, the patient information sheet is sent alongside the instructions for the procedure by mail or email at least 2 days prior to the procedure.

4. The patient reads the supplied information and is invited to contact the endoscopy fellow or the advanced endoscopy nurse coordinator prior to the day of the procedure if with any doubts.

5. Once admitted into the pre-endoscopy chairs/bed on the day of the procedure, the patient is approached by one of the investigators/co-investigators to discuss the procedure and the optional participation in the study. An interpreter will be used if required.

6. If the patient verbally agrees to participate and the procedure is confirmed as likely to take under or equal to 20 minutes, the informed consent form will then be signed.

7. If the patient decides not to participate, the procedure will be carried out as per the standard of care (anaesthetist to decide how supplementary oxygen will be delivered).

8. All randomised patients will be using both a standard nasal cannula and the mouthguard. Which one will be used for delivering oxygen will only be known to the Anaesthetist.

9. Data will be collected by one of the investigators/co-investigators or their delegates from the moment the patient enters the endoscopy room.

10. Once the procedure is finalised, the patient is transported to recovery for observation, as standard of care. Once awake and ready to be discharged, patients will receive a targeted symptoms questionnaire (Appendix 4). If any of the items are scored as moderate or worse, one of the investigators will be contacted and effort will be made to minimize the discomfort. Another assessment will take place 30 minutes after the first assessment in this instance.

11. PRAEs and SRAEs will be monitored during this period as standard of practice.

12. All patients will be discharged with an orientation letter advising on possible adverse events from the procedure/sedation as standard of care.

13. The study results are intended to be translated into abstract(s)/manuscript(s) and submitted to internationally recognized peer reviewed medical conferences and journals.

14. All records of patients who participate in the trial will be marked so they are not destroyed by medical records for at least 15 years.

b. STANDARD CARE AND ADDITIONAL TO STANDARD CARE PROCEDURES

Standard Care Procedures			Additional To Standard Care		
Procedure	**Time/Visit**	**Dosage/Volume**	**Procedure**	**Time/Visit**	**Dosage/Volume**
Supplemental oxygen through SNC	Any	Up to 2l/min	None	None	None
Supplemental oxygen through HFMG	Any	Up to 20l/min	None	None	None
Supplemental oxygen through HFNC	Any	Up to 60l/min	None	None	None

All the three oxygen delivery modalities described above are already available to any endoscopic procedure. The decision on which one to use, as per standard of care, relies solely on the anaesthetist expertise/subjective evaluation. In our study, the decision on which device will be initially used will be done through a previously randomised order.

c. RANDOMISATION

Prior to enrolment of the first patient, allocation will be pre-defined through an online research randomiser (https://www.randomizer.org). The order produced by this tool will be translated into 300 sealed opaque envelopes containing a folded slip with either the intervention (i.e. HFMG) or the control (i.e. COT) group will be organised by an independent person from the Gastroenterology Department who is not a member of the research team. The envelopes will have written on them the number in which they should be consecutively opened as per the randomisation tool (labelled from 1 to 300). The first 150 envelopes will be kept at Austin hospital and the last 150 envelopes will be kept at Repatriation hospital. If any of the centres reach 5 envelopes while the other centre has still over 10 envelopes left, half of the envelopes will be randomly selected and sent to the other centre. All envelopes will be kept in the nurse unit manager's office and will be given to the anaesthetist performing the sedation for the procedure after the patient has consented for the study. Only the clinical care team (e.g. anaesthetist, endoscopist, nurses), not the patient, will be notified of the randomisation results.

D. STUDY METHODOLOGY

Data on demographics and medical conditions will be collected from the medical records as per Appendix 1. Information on the procedure from the anaesthetist and endoscopist perspectives will be collected during and shortly after the procedure as per Appendices 2 and 3, respectively. Data on participant's symptoms post-procedure will be collected as per

Appendix 4. This study will be registered at clinicaltrials.gov prior to the enrolment of the first participant.

6. Study Population

a. Recruitment Procedure

All patients scheduled for an elective endoscopic procedure deemed by one of the investigators as expected to take 20 minutes or less and with low risk of sedation related adverse events (SRAE) will be sent the patient information sheet alongside to their notice for the endoscopic procedure by mail. On the day of the procedure, one of the investigators will consent the patient for the study.

Patients with low risk for SRAE will be determined according the presence of any of the following criteria: BMI ≥35, ASA IV or Mallampati 4.

b. Inclusion Criteria

- Patients referred for upper gastrointestinal endoscopic procedures predicted to last less or equal to 20 minutes (e.g. diagnostic gastroscopies)
- Age > 18 years
- Ability to give informed consent

c. Exclusion Criteria

- Pregnancy
- Supplementary O2 dependency
- Emergency procedures
- Deemed by performing endoscopist as long (>20 minutes) procedure before randomisation
- Patients with high risk for SRAE
- Capsule endoscopy procedure

d. Consent

Individual consent will be sought on the day of the procedure, after the participant had time to read through the participant information sheet (sent by mail to all eligible participants with the notice of their endoscopic procedure).

7. Participant Safety and Withdrawal

a. Risk Management and Safety

All patients will be managed according to established best practice according to international research and consensus on endoscopic procedures. Treatment does not differ according to whether or not the patient chooses to participate in the study.

Most eligible participants will not be the regular patients of the investigators or the endoscopists involved in the study. This is because the majority of the patients are referred from other medical specialists or GPs to our Endoscopy Unit. Vigilance in explaining the

voluntary nature of participation will be exercised for all patients. It will be emphasized that a decision not to enroll in the study will have no ramifications whatsoever for the patients care and ongoing relationship with the treating medical team.

b. Handling of Withdrawals

In accordance with the Declaration of Helsinki and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Good Practice Guidelines, a participant is free to withdraw from the study at any time for any reason without prejudice to their future medical care by the physician or the institution. The Investigator may also withdraw the participant at any time in the interests of patient safety. Should a participant decide to withdraw, all efforts will be made to complete and report the observations as thoroughly as possible. Participants may be removed from the study if one or more of the following events occur:

- Withdrawal of consent
- Decision made by the investigators that removal from the study is in the patient's best medical interest.
- Study stopped by ethics/regulatory authorities

The primary reason and additional reasons for withdrawal will be recorded in the participants' medical record.

c. Replacements

Withdrawal of patients or losses after randomisation have been accounted for when calculating the sample size. No replacement will be sought for losses after randomisation.

8. Statistical Methods

a. Sample Size Estimation & Justification

The study aims to enroll 300 patients (150 in each arm), anticipating a half the difference found by Lin et al. when comparing the high-flow nasal cannula at 40-60L/min with a flow of 2L/min (Lin et al. 2019. P. 597). The sample size was calculated for an 8.4% difference in desaturation for two independent groups (1.0% versus 9.4%) and dichotomous variable, enrolment ratio of 1:1.

b. Power Calculations

Two-tailed 0.05 alpha error and power of 80% were used for the sample size calculation. In addition, a 10% loss after randomisation was accounted for.

c. Statistical Methods To Be Undertaken

Collected data will be summarised as mean ± standard deviation (SD) or median (25th and 75th percentile) for continuous data, and as frequency and percentages for categorical data. For continuous data, the characteristics and outcomes for the two intervention groups were compared using Student's t -test or Wilcoxon-Mann-Whitney test based on the normality assumption. Categorical data will be compared with Chi-square or Fisher's exact test as

appropriate. A p value of < 0.05 will be considered significant. Statistical analyses will be performed with SPSS statistical software (IBM Corp. 2020. IBM SPSS Statistics, Version 26.0. Armonk, NY).

9. Storage of Blood and Tissue Samples

a. Details of where samples will be stored, and the type of consent for future use of samples

Not applicable. No samples collected for this study.

10. Data Security & Handling

a. Details of where records will be kept & How long will they be stored

All original identifiable hardcopy datasheets will be stored in a locked research office at the Endoscopy unit at the Harold Stokes Building (Austin Health), and will be assessed only by medical practitioners or nurses. The data will be retained for a period of 15 years according to the Australia Code of Conduct.

b. Confidentiality and Security

Identifiable electronic copies will be maintained in password-protected desktops, laptops or USBs/external hard drives. Patient data will then be de-identified for statistical analyses.

c. Ancillary data

Not applicable. No ancillary data will be collected for this study.

11. References

Dimou, F, Huynh, S, Dakin, G, Pomp, A, Turnbull, Z, Samuels, JD & Afaneh, C 2019, 'Nasal positive pressure with the SuperNO2VA™ device decreases sedation-related hypoxemia during pre-bariatric surgery EGD', Surgical Endoscopy, vol. 33, no. 11, pp. 3828-3832.

Lin, Y, Zhang, X, Li, L, Wei, M, Zhao, B, Wang, X, Pan, Z, Tian, J, Yu, W & Su, D 2019, 'High-flow nasal cannula oxygen therapy and hypoxia during gastroscopy with propofol sedation: a randomized multicenter clinical trial', Gastrointestinal Endoscopy, vol. 90, no. 4, pp. 591-601.

Smith, ZL, Mullady, DK, Lang, GD, Das, KK, Hovis, RM, Patel, RS, Hollander, TG, Elsner, J, Ifune, C & Kushnir, VM 2019, 'A randomized controlled trial evaluating general endotracheal anesthesia versus monitored anesthesia care and the incidence of sedation-related adverse events during ERCP in high-risk patients', Gastrointestinal Endoscopy, vol. 89, no. 4, pp. 855-862.