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| **.1** | **Study Title** | Laryngoscope-Bougie Guided I-gel Insertion in difficult airways: A feasibility trial |
| **PI** | Dr Jonathan Shachar – anaesthetic registrar |
| **Ref** | 2024/ETH00038 |
| **Reviewer** | Robert Schmidli |
| **What is your recommendation for this item?** |
| [ ] Approve without changes [x] Approve out of session with changes [ ] Not Approve and resubmit* *Aims of study in all documentation (including PICF) need to be changed to indicate that the study will only provide descriptive statistics regarding the proposed technique*
* *Protocol and PICF needs to state that proposed treatment differs from usual standard of care and that the treatment is experimental*
* *Feedback questionnaire to anaesthetists needs to be included in submission and needs to be expanded to allow adequate information to be conveyed to researchers*
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| **Review**  |
| * 1. **Research Merit and Integrity (NS1.1):**
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| **Does the research proposal ask a relevant/worthwhile research question?**  | **Yes/~~No~~** |
| Yes. Possibility of reducing risk of anaesthetic mishaps in at-risk patients |
| **Has the researcher justified the need for this research?** | **Yes/~~No~~** |
| Study will use a laryngoscope and bougie to guide supraglottic device insertion (Laryngoscope-Bougie Guided Insertion, LGBI), with the aim of increasing the first attempt success rate. Research shows superior rates of first attempt success using bougie with a similar supraglottic airway device compared to digital (blind) insertion (DI) giving mixed results, but no data exists for i-gel device. Comparison of i-gel with LBGI exists for low-risk, but not high-risk airways. Success rate of DI in low-risk, non-paralysed patients 88% to 96%. Improvement in technique likely to reduce risk of local damage associated with intubation. I-gel has very good safety record. |
| **Will the proposed methodology answer the research question(s)?**  | **~~Yes~~/No** |
| Aim is to assess whether LBGI with i-gel increases first attempt success in patients with risk factors for difficult supraglottic airway insertion. Secondary objectives include assessment of airway trauma, time taken for insertion & anaesthetist acceptance. 12-month study. i-gel device has an airway and drain tube (for insertion of nasogastric tube). Drain tube primed with 14 Fr bougie. Posterior glottis identified under direct vision with laryngoscope, bougie advanced 5-10cm into the oesophagus. i-gel then fed into position to cover laryngeal framework. i-gel is removed while bougie is held in position. Device is included in the Australia Register of Therapeutic Goods. Participants must have BMI>30 plus one of: poor dentition, reduced cervical spine movement, short thyromental distance, limited mandibular protrusion. Exclusions: predicted duration surgery >2h, high risk aspiration, distorted upper airway, ventilatory disease, inability to bag mask, history of difficult intubation etc. Suitability and airway assessment performed during recruitment. ``Clarification: “As such there will be no prescribed deviation from the standard of care provided by the anaesthetists or mandated by ANZCA.”Feedback questionnaire looks very brief, and has not been included in submissionAdverse events – criteria appear quite narrowUse of term “number needed to treat” is unclear (Finance and Resource Use)As this is a feasibility study with no control group, the primary research question is not answered by this study. It will only provide descriptive statistics, which can be compared to historical dataConsent form does not need to repeat as much information from PICF |
| **Is the protocol following good clinical practice?** | **Yes/~~No~~** |
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| **Are the power calculations, indicating the number of recruits required, accurate?** | **~~Yes~~/No** |
| No power calculations |
| **Is the proposed statistical analysis robust and accurate enough to deal with the data generated?** | **~~Yes~~/No** |
| Appears credible but I do not have sufficient expertise to assess this |
| **Are the drug safety issues fully addressed?** | **Yes/No** |
| N/A |
| **Are the risks to recruits detailed in the proposal listed fully and completely in the PICF?** | **Yes/~~No~~** |
| Statement that similar techniques have been trialled should be added to PICF to provide reassurance“Cut to tongue, lip or gums” is quoted to be 16% for LGBI, compared to 7.6% in similar studiesAs there is no control group, the study cannot accurately determine whether the i-gel is more safe or effective than traditional methods (p1, PICF)A link to a reputable video would be very useful in PICF |
| **Suggested Comments to the Researcher from HREC**  |
| **RMI (NS1.1)** |
| **Do you have comments for the HREC to consider against any of the other NS criteria?** | **Yes/No** |
| **Justice (NS1.4)** |
| **Beneficence (NS1.6)** |
| **Respect (NS1.10)** |
| **General Comments on Risks and Benefits** |