All items from the World Health Organization Trial Registration Data Set (SPIRIT item 2b)

| **Data category** | **Information** |
|---|---|
| Primary registry and trial identifying number | ClinicalTrials.gov<br>NCT04142840 |
| Date of registration in primary registry | 26 October 2019 |
| Secondary identifying numbers | DP-TEA 2.0 |
| Source(s) of monetary or material support | Youth Program of National Natural Science Foundation of China (No. 81801096, to Song Zhang) |
| Primary sponsor | Renji Hospital |
| Secondary sponsor(s) | / |
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| Public title | Comparing the Effects of Dexmedetomidine versus Propofol on the Treatment of Emergence Agitation in Adult Patients after General Anesthesia |
| Scientific title | Comparing the Effects of Dexmedetomidine versus Propofol on the Treatment of Emergence Agitation in Adult Patients after General Anesthesia: study protocol for a randomized controlled trial (DP-TEA Trial) |
| Countries of recruitment | China |
| Health condition(s) or problem(s) studied | Emergence agitation after general anesthesia |
| Intervention(s) | ***Intervention Name:*** Dexmedetomidine group<br>***Intervention Description:*** Once emergence agitation occurs, the participant assigned to dexmedetomidine group will be infused with a single dose of 0.7ug/kg dexmedetomidine.<br><br>***Intervention Name:*** Propofol group<br>***Intervention Description:*** Once emergence agitation occurs, the participant assigned to propofol group will be infused with a single dose of 0.5mg/kg propofol. |

| Data category | Information |
|---|---|
| Key inclusion and exclusion criteria | ***Inclusion criteria:***<br>• adult patients aged 18-65 years of both genders, with American Society of Anesthesiologists (ASA) classification I or II developing EA after general anesthesia with verbal consent.<br>***Exclusion Criteria:***<br>• age younger than 18 years or older than 65 years;<br>• ASA classification ≥III;<br>• preoperative lung dysfunction (including pneumonia, atelectasis, acute respiratory distress syndrome, acute lung injury, and so on);<br>• preoperative heart dysfunction (including sever cardiac coronary disease, unstable angina, left ventricular ejection fraction≤30％, sick sinus syndrome, bradycardia: heart rate (HR)≤50beats/min, the second or third degree of atrioventricular block);<br>• history of mental disease;<br>• uncontrolled hypertension (baseline: systolic blood pressure (SBP)≥160mmHg or diastolic blood pressure (DBP)≥110mmHg);<br>• enrolled in other researches within 90 days;<br>• allergic to dexmedetomidine or propofol;<br>• 10) body mass index (BMI) less than 18 kg/$m^2$ or more than 30 kg/$m^2$. |
| Study type | Interventional<br>***Allocation:*** randomized<br>***Intervention model:*** parallel<br>***Masking:*** Blind to patients, outcome assessors, care providers, data collectors and statisticians.<br>***Primary purpose:*** recovery quality after general anesthesia research |
| Date of first enrolment | 1 November 2019 |
| Target sample size | 120 |
| Recruitment status | Enrolling |
| Primary outcome(s) | The primary outcome is the proportion of patients having a recurrent EA within 15min after intervention in the PACU. EA is defined as a restless state with a Riker's Sedation-Agitation Scale (RSAS) score of 5 or more |

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| Key secondary outcomes | • RSAS scores when first EA occurs and at $t_2$;<br>• Vital signs at $t_0$, $t_1$, $t_2$, $t_3$, including HR, MBP and $SpO_2$;<br>• Proportion of patients requiring rescue sufentanil during resuscitation in the PACU: an 11-point numerical rating scale (NRS) is used to assess postoperative pain whenever patients ask for pain medication. If a NRS score is≥5, additional 5-10μg sufentanil will be injected as rescue medication.<br>• Proportion of patients with PONV, evaluated by a four-point PONV Scale during resuscitation in the PACU;<br>• Time to discharge from the PACU;<br>• Proportion of patients with adverse events after intervention in the PACU, including oxygen desaturation (defined as SpO2<90%, regarded as severe desaturation when SpO2<85%), severe bradycardia (defined as HR<50 beats/min), shivering, dizziness, laryngospasm, severe coughing, and reintubation;<br>• Recovering quality score assessed at 24 hours after surgery using 40-item quality of recovery scale (QoR-40) |
| Ethics Review | • Status: Approved<br>• Date of approval: 14th, October 2020<br>• Name and contact details of Ethics committee(s): the Ethics committee of Renji Hospital affiliated to Shanghai Jiao Tong University School of Medicine |
| Completion date | • We expect to complete the study on December 31, 2021. |
| Summary Results | • / |
| IPD sharing statement | • The data that support the findings of this study will be available from the corresponding author upon reasonable request. |