بیمارستان قلب شهید رجایی

مقایسه تاثیر آرام بخشی با دکس مدتو میدین و پروپوفول در کیفیت خواب بیماران پس از جراحی قلب

شناسنامه طرح

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توضیحات:	احتراما اصلاحات درخواستی در متن پروپوزال انجام شد و فایل نهایی پروپوزال ضمیمه شده است ۹۹/۹/۱۹
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مجری / همکاران

نام و نام‌خانوادگی	سمت در طرح	نوع همکاری	توضیحات
رسول آذرفرین	مجری اصلی / نویسنده مقاله	استاد راهنما	
محسن ضیائی فرد	همکار طرح و نویسنده مقاله	طراحی و تدوین طرح	
رسول فراست کیش	همکار طرح	معرفی بیماران	
آذین علیزاده اصل	همکار طرح	معرفی بیماران	
محمدضیاء توتونچی قربانی	همکار طرح	نظارت بر اجرای طرح	
ناهید عقدائی	همکار طرح	معرفی بیماران	
مرضیه یوسفی	همکار طرح	بررسی فرمها و ثبت مشخصات بیماران	
تورج بابائی	ناظر	نظارت بر اجرای طرح	

دانشکده/مرکز مربوطه

رده	نوع ارتباط با مرکز
مرکز تحقیقات کاردیو انکولوژی	وارد کننده

متون پیشنهاد

آیتم اطلاعات تفضیلی	متن
جدول متغیرها	جدول متغیرها پیوست شده است
جدول زمان بندی	جدول زمان بندی ۶ ماهه پیوست شده است.
نقایص و مشکلات کارهای قبلی	اکثر مطالعات قبلی به میزان سداسیون و بی دردی و عوارض مربوطه در بیماران بعد از جراحی قلب پرداخته اند. مطالعاتی که روی کیفیت خواب کار کرده اند عموما روی بیماران غیر قلبی تحقیق کرده اند و ما اطلاعات کمی در مورد کیفیت خواب بیماران پس از جراحی قلب در آی سی یو داریم. لذا با انجام این طرح قصد داریم کیفیت خواب بیماران پس از عمل قلب باز را با مقایسه دو داروی مرسوم دکس مدتمیدین و پروپوفول مقایسه نماییم
بیان مسئله	There are more than ۲ million cardiac surgical procedures performed worldwide each year (۱). Although the mortality of cardiac surgical procedures has significantly decreased due to the great improvement in surgical techniques, the major complication rates are as high as ۱۴.۴٪ to ۳۰.۱٪ (۲). These complications are associated with a prolonged hospital stay, an increase in resource utilization, and higher health care costs (۳). Thus, the postoperative care of these patients remains to be optimized. It is accepted that sedation is an important component of postoperative management after cardiac surgery (۴) and has an important effect on patient outcomes (۵). Many patients who are hospitalized in ICU experience reduced quality and quantity of sleep (۶) with regard to mental and environmental factors). . Recently, Song et al. compared the effect of using dexmedetomidine during the daytime operation on postoperative sleep quality and pain of patients. The results of this study showed that using dexmedetomidine during the daytime operation can better improve postoperative sleep quality and pain than nighttime operation in patients undergoing laparoscopic abdominal surgeries (16). Lu et al. evaluated the effect of dexmedetomidine on the sleep quality of patients without mechanical ventilation in ICU. The results of this study showed that Dexmedetomidine is a clinically effective and safe

sedative for the highly selected critically ill patients without endotracheal tube and mechanical ventilation in the ICU to increases total sleep time and improve sleep efficiency (17). Lewis et al. evaluated whether the quantity and quality of sleep may be improved by the administration of propofol to adults in the ICU. They found insufficient evidence to determine whether the administration of propofol would improve the quality and quantity of sleep in adults in the ICU (18). Kondili et al. evaluated the effect of propofol administration on sleep quality in critically ill patients ventilated on assisted modes. The results of this study showed that propofol administration to achieve the recommended level of sedation suppresses the REM sleep stage and further worsens the poor sleep quality of these patients (19). Liu et al. compared the effects of dexmedetomidine and propofol sedation on outcomes in adult patients after cardiac surgery. The results of this study showed that dexmedetomidine associated with a lower risk of delirium, a shorter length of intubation, but a higher incidence of bradycardia as compared to propofol. There were no statistical differences in the incidence of hypotension or atrial fibrillation or the length of intensive care unit stay between dexmedetomidine and propofol sedation regimens (13). Maldonado et al. investigated the effects of postoperative sedation (protocol and dexmedetomidine) on the development of delirium in patients undergoing cardiac-valve procedures. The results of this study showed that postoperative sedation with dexmedetomidine was associated with significantly lower rates of postoperative delirium (20). Djaiani et al. compared postoperative delirium after cardiac surgery in patients who received dexmedetomidine with patients who received propofol. The results of this study showed that when compared with propofol, dexmedetomidine sedation reduced incidence, delayed onset, and shortened duration of postoperative delirium in patients after cardiac surgery (21). Corbett et al. assessed patient-perceived satisfaction with coronary artery bypass graft surgery after administration of dexmedetomidine or propofol for ICU sedation. The results of this study showed that despite the theoretical advantages of dexmedetomidine to improve overall patient satisfaction, the two agents provide similar responses to amnesia and pain control. According, dexmedetomidine does not seem to have any advantage compared with propofol for short-term sedation after coronary artery bypass graft surgery (22). Herr et al. compared dexmedetomidine-based to propofol-based sedation after coronary artery bypass graft surgery in the ICU. The results of this study showed that mean times to weaning and extubation were similar in both group, although fewer dexmedetomidine patients remained on the ventilator beyond 8 hours. Morphine use was significantly reduced in the dexmedetomidine group. No ventricular tachycardia occurred in the dexmedetomidine-sedated patients compared with 5% of the

propofol patients (p = 0.007). Respiratory rates and blood gases were similar. Fewer dexmedetomidine patients received beta-blockers (p = 0.014), antiemetics (p = 0.015), nonsteroidal anti-inflammatory drugs (p < 0.001), epinephrine (p = 0.030), or high-dose diuretics (p < 0.001) (23). Eremenko et al. compared the efficacy of Dexmedetomidine and Propofol for short-term controlled sedation and analgesia in the early postoperative period after cardiac surgery. The results of this study showed that dexmetomedine provides its own analgesic effect and shortens the length of patient's stay in ICU. Bradycardia was noted more frequently in Dexmedetomidine while arterial hypotension, general malaise, and delirium in the Propofol group (24). Karaman et al. compare the effects of propofol and dexmedetomidine infusions on extubation times, hemodynamic and respiratory functions, complication rates, and patient satisfaction scores in patients undergoing coronary artery bypass graft surgery. The results of this study showed that dexmedetomidine can easily be preferred over propofol in fast-track cardiac anesthesia due to its significant advantages of shorter extubation time and higher (postoperative patient satisfaction scores (25	
Several studies, have shown that dexmedetomidine is associated with a decrease in the incidences of postoperative complications in patients undergoing cardiac surgery (۴, ۸, ۹). Ji et al. reported in their results that 'perioperative dexmedetomidine use associate with a decrease in postoperative mortality up to ۱ year and decrease the incidence of postoperative complications and delirium in patients undergoing cardiac surgery' (۸). A meta-analysis study by Geng et al. in ۲۰۱۶, revealed that the perioperative use of dexmedetomidine in patients undergoing cardiac surgery can reduce the risk of postoperative ventricular tachycardia and delirium, atrial fibrillation, shorter length of stay in intensive care unit (ICU) and hospitalization, but it may increase the risk of bradycardia and hypotension (۹). Current guidelines suggest that sedation strategies using nonbenzodiazepine sedatives (either propofol or dexmedetomidine) may be preferred over sedation with benzodiazepines to improve clinical outcomes in mechanically ventilated adult ICU patients (۵). Propofol, is a preferred sedative in ICU after cardiovascular surgery because it offers advantages over benzodiazepines regarding the lack of accumulation, quick onset, easy adjustment, and fast recovery after discontinuation (۱۰). Adverse effects associated with propofol included pain on injection, hypotension, bradycardia, respiratory depression, and hypertriglyceridemia. Propofol infusion syndrome is a rare but life-threatening adverse effect and remains a concern (۱۱).	ضرورت اجرا
There are more than 2 million cardiac surgical procedures performed	ضرورت اجرا

worldwide each year (1). Although the mortality of cardiac surgical procedures has significantly decreased due to the great improvement in surgical techniques, the major complication rates are as high as 14.4% to 30.1% (2). These complications are associated with a prolonged hospital stay, an increase in resource utilization, and higher health care costs (3). Thus, the postoperative care of these patients remains to be optimized. It is accepted that sedation is an important component of postoperative management after cardiac surgery (4) and has an important effect on patient outcomes (5). Many patients who are hospitalized in ICU experience reduced quality and quantity of sleep with regard to mental and environmental factors (6). Sleep has an important role in cardiovascular function. Its deprivation intensifies anxiety, irritability, and anger, and increases the heart rhythm and myocardial oxygen demand in a frequent and dangerous cycle (7). Several studies, have shown that dexmedetomidine is associated with a decrease in the incidences of postoperative complications in patients undergoing cardiac surgery (4, 8, 9). Ji et al. reported in their results that 'perioperative dexmedetomidine use associate with a decrease in postoperative mortality up to 1 year and decrease the incidence of postoperative complications and delirium in patients undergoing cardiac surgery' (8). A meta-analysis study by Geng et al. in 2016, revealed that the perioperative use of dexmedetomidine in patients undergoing cardiac surgery can reduce the risk of postoperative ventricular tachycardia and delirium, atrial fibrillation, shorter length of stay in intensive care unit (ICU) and hospitalization, but it may increase the risk of bradycardia and hypotension (9). Current guidelines suggest that sedation strategies using nonbenzodiazepine sedatives (either propofol or dexmedetomidine) may be preferred over sedation with benzodiazepines to improve clinical outcomes in mechanically ventilated adult ICU patients (5). Propofol, is a preferred sedative in ICU after cardiovascular surgery because it offers advantages over benzodiazepines regarding the lack of accumulation, quick onset, easy adjustment, and fast recovery after discontinuation (10). Adverse effects associated with propofol included pain on injection, hypotension, bradycardia, respiratory depression, and hypertriglyceridemia. Propofol infusion syndrome is a rare but life-threatening adverse effect and remains a concern (11). Dexmedetomidine is a novel sedative analgesic used after cardiovascular surgery does not cause respiratory depression and its selective α2 action may provide more hemodynamic stability. The net effect of dexmedetomidine action is a significant reduction in circulating catecholamines with a slight decrease in blood pressure and a modest reduction in heart rate (12). However, it is uncertain whether dexmedetomidine is better than propofol for sedation and quality of sleep in patients after cardiac surgery (13). The degree of sedation or agitation in critically ill patients is typically assessed with

the Richmond Agitation and Sedation Scale (RASS). The RASS is a validated and reliable method to assess patients' levels of sedation in the ICU (14). Also, the St Mary's Hospital Sleep Questionnaire is a suitable sleep assessment tools (15). A ccordingly, we conducted a prospective, randomized, comparative study to compare the suitability (efficacy and safety) of dexmedetomidine versus propofol for patients admitted to the ICU after cardiovascular surgery.	
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اهداف: هدف اصلی، اهداف اختصاصی، هدف کاربردی

اهداف اصلی

Comparison of the effect of sedation with dexmedetomidine and propofol on sleep quality in patients after cardiac surgery

اهداف ویژه

- Evaluation of preoperative sleep quality in patients who will undergoing cardiac surgery.
- Evaluation and comparison of sleep quality in patients in the two groups of dexmedetomedine and propofol on one, two and three days after surgery.

- Evaluation and comparison of sedation quality in patients in the two groups of dexmedetomedine and propofol on one, two and three days after surgery.
- Evaluating the effect of clinical demographic variables on postoperative sleep quality.
- Evaluation of duration of surgery, cardiac surgery types, postoperative extubation times, patient satisfaction, postoperative adverse events, stay in the ICU, need for additional opioid injections, type, and frequency of side effects.

اهداف کاربردی

To determine the best nonbenzodiazepine sedatives (dexmedetomidine or propofol) on sleep quality in patients admitted to the ICU after cardiac surgery.

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فرضیات یا سوالات پژوهشی

فرضیه (های) پژوهش

- Dexmedetomidine improve sleep quality after cardiac surgery.
- Propofol improve sleep quality after cardiac surgery.
- Dexmedetomidine reduces agitation of patients after cardiac surgery.

	• Propofol reduces agitation of patients after cardiac surgery. • Dexmedetomidine creates appropriate levels of sedation in the ICU patients. • Propofol creates appropriate levels of sedation in the ICU patient
روش اجرا	This study will be conducted on patients admit to the ICU after cardiovascular surgery in Shahid Rajaei Cardiovascular, Medical and Research center.. Informed written consent will obtain from their relatives. Based on the ۹۵٪ confidence interval of the intraclass correlation coefficient (ICC) estimate, values equal ۰.۷۵, in order to have ۸۰٪ power with error type ۱, we required at least ? ICU patients who underwent cardiac surgery. All patients will give general anesthesia which will induce: midazolam (۵–۱۰ mg), fentanyl (۲۵۰–۵۰۰ μg) or sufentanil (۲۵–۵۰ μg), and rocuronium bromide (۰.۶–۱.۲ mg/kg) with arterial line (۲۲-gauge plastic cannula) will insert for invasive blood pressure monitoring in the left radial artery or in the non-dominant hand. The maintenance infusion include: midazolam (۱ μg/kg/min), atracurium (۱۰ μg/kg/min), fentanyl (۰.۱ μg/kg/min) doses will predicted in patients for ۳ to ۴ hours. At the end of the operation, patients will admit directly to the cardiothoracic ICU. The patients will mechanically ventilate, assess for ۱۲ h in the postoperative period. Patients will ventilate by the volume-assist control mode with a tidal volume (TV) of ۸–۱۰ mL/kg of predicted body weight. The FIO۲ and respiratory rate (RR) adjustments will be made according to routine blood-gas analyses to maintain the partial pressure of arterial oxygen (PaO۲) between ۸۰ and ۱۰۰ mm Hg and partial pressure of arterial carbon between ۳۵ and ۴۰ mm Hg. Patients after cardiovascular surgery aged above ۱۸ years will include in the study. These patients will exclude if they received both dexmedetomidine and propofol concomitantly for the primary sedation or an alternative agent as the primary sedation, had a prior solid organ transplant, or will pregnant or lactating. Other exclusion criteria will include as follows: acute severe neurological disorder, mean arterial pressure (MAP) <۵۵ mm Hg despite appropriate intravenous volume replacement and vasopressors, HR <۵۰/min, atrioventricular-conduction block Grade II or III (unless pacemaker installed), patients using alpha-۲ agonists or antagonists within ۲۴ h before operation. Patients will randomly divide into two groups (A and B), which will be prescribed dexmedetomidine and propofol, respectively. Randomization in the included patients will be done in the form of quadruple blocks using the randomization table extracted from www.randomization.org and patients will be randomly assigned to each of the two study groups. The starting maintenance infusion fentanyl doses will ۵۰ μg/h in

patients in either group after admitted to the cardiothoracic ICU. The infusion dose of dexmedetomidine (precedex) will ۰.۵ µg/kg/h in group A and ۵۰ µg/kg/min propofol in group B in ۶ hours (at the time of extubation in both groups). The RASS will use to assess patients' levels of sedation in all patients. RASS is a ۱۰-point scale, with four levels of anxiety or agitation (+۱ to +۴ [combative]), one level to denote a calm and alert state (۰), and ۵ levels of sedation (-۱ to -۵) culminating in unarousable (-۵). The values and definitions for each level of agitation and sedation are displayed in Table ۱, as are the instructions for assessment, as previously described (۱۶). Evaluation of sleep quality will study using Mary's Hospital Sleep Questionnaire (SMHSQ).

The RASS will be completed by the fellowship of cardioanesthesia the night before surgery and after extubation and patient awareness. Evaluation of sleep quality will study using Mary's Hospital Sleep Questionnaire (SMHSQ). The SMHSQ is a tool specifically designed to assess sleep in patients, testing the duration and quality of sleep the previous night while they are in the hospital. The items inquire about sleep issues, including latency, restlessness, insomnia, and alertness in the morning. This scale has ۱۴ multiple choice questions with short answers. This ۱۴-item questionnaire was designed to assess sleep quality in patients admitted to the hospital the night before and has the ability to be repeated (Table ۲). The SMHSQ will be completed by the fellowship of cardioanesthesia after surgery. Thefelloowship will not aware of the patient's medications (dexmedetomidine or propofol).

Statistical analyses were performed with SPSS ۱۵ for Windows (SPSS Inc., Chicago, Illinois). Data were expressed as mean values ± standard deviation for interval and count (٪) for categorical variables. All variables were tested for normal distribution with the Kolmogorov-Smirnov test. Categorical values were compared by Chi-square test or Fisher's exact test. To compare the mean variables between two groups, an independent t-test or Mann-Whitney U test was used. Continuous variables were compared using the two-tailed Wilcoxon test. Repeated measures ANOVA followed by Bonferroni post-test was used to assess parametric distributions. For non-parametric distributions Friedman test was applied. P values <۰.۰۵ were considered significant.

مشخصات ابزار جمع

ابزار جمع آوری اطلاعات همان فرم گرد آوری داده های دموگرافیک و پرسشنامه

آوری اطلاعات و نحوه جمع آوری آن	Mary's Hospital Sleep Questionnaire (SMHSQ).است و همچنین برای ارزیابی سداسیو از پرسشنامه | Richmond Agitation-sedation Scale استفاده می شود
روش محاسبه حجم نمونه و تعدادآن	حجم نمونه پس از مشورت با اپیدمیولوزیست محترم مرکز، با استفاده از رفرنس ' Effects of dexmedetomidine on sleep quality of patients after surgery without mechanical ventilation in ICU ' و بر اساس متغیر sleep efficacy در گروه دریافت کننده دکسمدتومدین در مقایسه با گروه کنترل، و با ظن کلینیکی بهبود کیفیت خواب ۲۰ درصدی این دارو در مقایسه با پروپوفول به صورتهای زیر،ابتدا با ۹۰ powerدرصد و سپس ۸۰ power درصد، تعیین گردید: α= ۰.۰۵ β=۰.۱۰ p_1=۰.۸۹ p_2= ۰.۶۹ N=۸۶ با احتساب ریزش ۱۰٪ به دلیل post randomization exclusion ، تعداد ۹۴ بیمار در هر گروه در نظر گرفته شود α= ۰.۰۵ β=۰.۲۰ p_1=۰.۸۹ p_2= ۰.۶۹ N=۶۴ با احتساب ریزش ۱۰٪ به دلیل post randomization exclusion ، تعداد ۷۰

	بیمار در هر گروه در نظر گرفته شود **Reference:** Lu W, Fu Q, Luo X, Fu Sh, Hu K. Effects of dexmedetomidine on sleep quality of patients after surgery without mechanical ventilation in ICU. Medicine (Baltimore). ۲۰۱۷ Jun; ۹۶(۲۳):e۷۰۸۱.
ملاحظات اخلاقی	Study will be conduct after approval in institutional ethics committee and after Informed written consent be obtained from all of the patients. فرم پرسشنامه بدون نام و اطلاعات فردی بیمار خواهد بود و اطلاعات مربوط به بیمار به صورت محرمانه حفظ خواهد شد. • بیمار هیچ هزینه ای را برای اجرای طرح پژوهشی پرداخت نخواهد کرد. • در صورت بروز عارضهای برای بیمار که ناشی از پژوهش حاضر باشد. کلیه هزینه های مربوط به درمان و رفع عوارض به عهده مجریان طرح خواهد بود.
محدودیتهای اجرایی طرح وروش کاهش آنها	Some patients and their families may refuse to enter the study. Accordingly, these patients will exclude from study. There will be no change in the routine treatment of patients with the exclusion of these patients from the study.
معیارهای ورود (فقط مربوط به طرحهای کارآزمایی بالینی)	بیماران کاندید جراحی الکتیو قلب ۱۸ سال و بالاتر بیمار انتوبه نباشد

	هوشیاری کافی جهت ارتباط کلامی داشته باشد سابقه جراحی قلب نداشته باشد سابقه سکته مغزی نداشته باشد
معیارهای خروج (فقط مربوط به طرحهای کارآزمایی بالینی)	ارست قلبی حین یا بلافاصله پس از عمل اغما یا عدم هوشیاری پس از عمل استفاده از اکمو یا IABP
چگونگی تصادفی سازی و Concealment (فقط مربوط به طرحهای کارآزمایی بالینی)	Random permuted blocks (۴ patient in each block) with concealment of randomization list from main researcher
تعریف گروه مداخله (فقط مربوط به طرحهای کارآزمایی بالینی)	The infusion dose of dexmedetomidine (precedex) will 0.5 µg/kg/h in group A after operation in ICU
تعریف گروه شاهدیامقایسه (فقط مربوط به طرحهای کارآزمایی بالینی)	µg/kg/min propofol in group B in 6 hours (at the time of 50 extubation in both groups)

چگونگی کورسازی (Blinding) (فقط مربوط به طرحهای کارآزمایی بالینی)	مطالعه یک سو کور است و بیماران از آنجایی که سداسیون می گیرند از نوع داروی سداتیو اطلاعی ندارند.
پیامدها اولیه (primary) ثانویه (secondary) ایمنی (Safety) (فقط مربوط به طرحهای کارآزمایی بالینی)	primary endpoint: Sleep quality after operation Scondary end points: Richmond agetation-sedatin scale, hemodynamic and respiratory parameters during and after operation
پیگیری (follow up) (فقط مربوط به طرحهای کارآزمایی بالینی)	follow up untill ۷۲ h after operation

ضرورت

There are more than 2 million cardiac surgical procedures performed worldwide each year (1). Although the mortality of cardiac surgical procedures has significantly decreased due to the great improvement in surgical techniques, the major complication rates are as high as 14.4% to 30.1% (2). These complications are associated with a prolonged hospital stay, an increase in resource utilization, and higher health care costs (3). Thus, the postoperative care of these patients remains to be optimized. It is accepted that sedation is an important component of postoperative management after cardiac surgery (4) and has an important effect on patient outcomes (5). Many patients who are hospitalized in ICU experience reduced quality and quantity of sleep with regard to mental and environmental factors (6). Sleep has an important role in cardiovascular function. Its deprivation intensifies anxiety, irritability, and anger, and increases the heart rhythm and myocardial oxygen demand in a frequent and dangerous cycle (7). Several studies, have shown that dexmedetomidine is associated with a decrease in the incidences of postoperative complications in patients undergoing cardiac surgery (4, 8, 9). Ji et al. reported in their results that 'perioperative dexmedetomidine use associate with a decrease in postoperative mortality up to 1 year and decrease the incidence of postoperative complications and delirium in patients undergoing cardiac surgery' (8). A meta-analysis study by Geng et al. in 2016, revealed that the perioperative use of dexmedetomidine in patients undergoing cardiac surgery can reduce the risk of postoperative ventricular tachycardia and delirium, atrial fibrillation, shorter length of stay in intensive care unit (ICU) and hospitalization, but it may

increase the risk of bradycardia and hypotension (9). Current guidelines suggest that sedation strategies using nonbenzodiazepine sedatives (either propofol or dexmedetomidine) may be preferred over sedation with benzodiazepines to improve clinical outcomes in mechanically ventilated adult ICU patients (5). Propofol, is a preferred sedative in ICU after cardiovascular surgery because it offers advantages over benzodiazepines regarding the lack of accumulation, quick onset, easy adjustment, and fast recovery after discontinuation (10). Adverse effects associated with propofol included pain on injection, hypotension, bradycardia, respiratory depression, and hypertriglyceridemia. Propofol infusion syndrome is a rare but life-threatening adverse effect and remains a concern (11). Dexmedetomidine is a novel sedative analgesic used after cardiovascular surgery does not cause respiratory depression and its selective α2 action may provide more hemodynamic stability. The net effect of dexmedetomidine action is a significant reduction in circulating catecholamines with a slight decrease in blood pressure and a modest reduction in heart rate (12). However, it is uncertain whether dexmedetomidine is better than propofol for sedation and quality of sleep in patients after cardiac surgery (13). The degree of sedation or agitation in critically ill patients is typically assessed with the Richmond Agitation and Sedation Scale (RASS). The RASS is a validated and reliable method to assess patients' levels of sedation in the ICU (14). Also, the St Mary's Hospital Sleep Questionnaire is a suitable sleep assessment tools (15). A ccordingly, we conducted a prospective, randomized, comparative study to compare the suitability (efficacy and safety) of dexmedetomidine versus propofol for patients admitted to the ICU after cardiovascular surgery.

جدول متغیرها

نام متغیر	نقش متغیر	نوع متغیر	نوع متغیر کمی – پیوسته است؟	نوع متغیر کمی – گسسته است؟	نوع متغیر کیفی — رتبه ای است؟	نوع متغیر کیفی — اسمی است؟	واحد اندازه گیری	تعریف کاربردی	نحوه اندازه گیری
سن	مستقل	کمی	☑	☐	☐	☐	سال	سن بیمار	پرسش
جنس	مستقل	کیفی	☐	☐	☐	☑	مرد زن	مرد زن	پرسش

مدت زمان عمل	مستقل	کمی	☑	☐	☐	☐	دقیقه	مدت عمل	مشاهده
مدت پمپ قلبی ریوی	مستقل	کمی	☑	☐	☐	☐	دقیقه	مدت پمپ	مشاهده
مدت کراس کلامپ	مستقل	کمی	☑	☐	☐	☐	دقیقه	مدت کراس کلامپ ائورت	مشاهده
مدت ونتلاسیون مکانیکی	مستقل	کمی	☑	☐	☐	☐	ساعت	زمان ورود به ای سی یو تا اکستوباسیون	مشاهده
هیپو تانسیون حین عمل	مستقل	کیفی	☐	☐	☐	☑	بلی، خیر	موارد فشار متوسط شریانی کمتر از ۶۵ حین عمل	mmHg
مدت اقامت در ای سی یو	وابسته	کمی	☑	☐	☐	☐	ساعت	زمان ورود تا خروج از ای سی یو	مشاهده
وقوع آریتمی حین یا بعد از عمل	مستقل	کیفی	☐	☐	☐	☑	بلی، خیر	هر نوع آریتمی خطرناک مثل VF Vtac Rapid AF حین یا پس از عمل	مشاهده یا گزارش پرستار
دریافت دکس یا پروپوفول	مستقل	کیفی	☐	☐	☐	☑	گروه مطالعه	دریافت نوع سداسیون پس از عمل بطور تصادفی شده	مشاهده
میزان سداسیون	وابسته	کمی	☑	☑	☐	☐	امتیاز	پرسشنامه آژیتاسیون سداسیون ریچموند	مشاهده
کیفیت خواب	وابسته	کمی	☑	☐	☐	☐	امتیاز	گزارش کیفیت خواب بر اساس پرسشنامه Mary's Hospital Sleep Questionnaire (SMHSQ)	مشاهده
دیرسیون تنفسی	وابسته	کیفی	☐	☐	☐	☑	بلی، خیر	افت اسباع اکسیژن یا اکسی متری به کمتر از ۸۸٪ پس از عمل	مشاهده

زمانبندی و مراحل اجرا

شرح مختصر مرحله	درصد مرحله	مدت اجرا – ماه	از تاریخ	تا تاریخ
پس از تایید پروپوزال در کمیته پژوهشی و اخلاق گرداوری داده ها شروع خواهد		۶	۱۳۹۹/۰۸/۲۸	۱۴۰۰/۰۲/۲۸

ملاحظات اخلاقی

شما اجازه مشاهده این فرم را ندارید

هزینه وسایل و مواد مورد نیاز

نوع	نام دستگاه/ وسیله/ مواد	تعداد مورد نیاز	قیمت دستگاه/ وسیله/ مواد – ریال	کشور سازنده	شرکت سازنده	شرکت فروشنده	محل تامین اعتبار	جمع کل هزینه به ریال

هزینه پرسنلی

نام و نام خانوادگی	توصیف دقیق فعالیتی که فرد در این تحقیق باید انجام دهد	کل حق‌الزحمه – ریال
مرضیه یوسفی(۲۰۴۲)	تدوین پروپوزال و نظارت بر اجرا و تهیه گزارش نهایی و مقاله	۲۰,۰۰۰,۰۰۰

جمع کل – ریال : ۲۰,۰۰۰,۰۰۰

هزینه آزمایشات و خدمات تخصصی

نام خدمت	نام مؤسسه ارائه کننده	تعداد یا مقدار لازم	قیمت واحد – ریال	قیمت کل – ریال
رکوردی یافت نشد				

هزینه مسافرت

مقصد	تعداد مسافرت در مدت اجرای طرح و منظور آن	نوع وسیله نقلیه	تعداد مسافرت	مبلغ
رکوردی یافت نشد				

هزینه کتب، نشریات و مقالات

نوع هزینه	توضیحات	مبلغ – ریال
سایر	تکثیر فرم ها	۱۰,۰۰۰,۰۰۰

جمع کل – ریال : ۱۰,۰۰۰,۰۰۰

سایر هزینه ها

نوع هزینه	مبلغ – ریال
منشی پیگیری پرونده ها و بیماران	۲۰,۰۰۰,۰۰۰

جمع کل – ریال : ۲۰,۰۰۰,۰۰۰

کل اعتبار درخواست شده

هزینه پرسنلی (هیات علمی و غیر هیات علمی)	هزینه مواد مصرفی	هزینه مواد غیر مصرفی	هزینه تجهیزات،موادوخدمات موجوددر مرکز	هزینه مسافرت	هزینه چاپ و تکثیر	سایر هزینه ها	جمع کل هزینه – ریال
۲۰,۰۰۰,۰۰۰					۱۰,۰۰۰,۰۰۰	۲۰,۰۰۰,۰۰۰	۵۰,۰۰۰,۰۰۰