

Pan African Clinical Trials Registry

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Trial #: PACTR201907779292947

Date of Approval: 16/07/2019 **Trial Status:** Registered in accordance with WHO and ICMJE standards

TRIAL DESCRIPTION

Public title	Effect of ketamine infusion on postoperative mood scores in patients undergoing D&C. A randomized double blinded controlled study
Official scientific title	Effect of ketamine infusion on postoperative mood scores in patients undergoing D&C. A randomized double blinded controlled study
Brief summary describing the background and objectives of the trial	Emotional and psychological effects following abortion are more common than physical side effects and can range from mild regret to more serious complications such as depression. Research published in 2011 concluded that there was a "moderate to highly increased risk of mental health problems after abortion." The researchers suggested that undergoing a termination increased the risk by 81 percent and attributed 10 percent of this risk to the termination itself. Women with a higher probability of having a negative emotional or psychological side effect include: Individuals who obtain an abortion in the later stages of pregnancy, Individuals without support from significant others or their partner, Women obtaining an abortion for genetic or fetal abnormalities [1] The Profile of Mood States (POMS) is a psychological rating scale published in 1971 used to assess transient, distinct mood states. This scale was developed by McNair, Droppleman, and Lorr [2]. The first edition of the Profile of Mood States scale is known as the POMS-Standard version or the POMS-long form. Multiple short versions were published later after rigorous validation processes. Advantages of using this assessment include the simplicity of administration and ease of participant understanding. POMS test allowed both positive and negative states to be measured and observed in a clinical setting. Furthermore, it may be used to measure the effectiveness of treatments such as, various psychotropic drug treatments. [3] Recent studies suggest that a single low-dose administration of ketamine can provide within a few minutes of its initiation a long-lasting effect on mood [4]. Ketamine has emerged as a rapid powerful antidepressant and anxiolytic with enduring effects that last a week after a single subanaesthetic dose in the range of 0.3 to 0.5mg/kg however, its underlying mechanisms are not clear [5] Interestingly, the half-life of ketamine is only 3 h, suggesting that its antidepressant effect is unrelated to continuous blocking of N-methyl-d-aspartate (NMDA) receptors; instead, ketamine may mediate synaptic plasticity to cause long-term behavioral changes [6].
Type of trial	RCT
Acronym (If the trial has an acronym then please provide)	
Disease(s) or condition(s) being studied	Anaesthesia,Mental and Behavioural Disorders,Nervous System Diseases
Sub-Disease(s) or condition(s) being studied	
Purpose of the trial	Prevention
Anticipated trial start date	19/07/2019
Actual trial start date	20/07/2019
Anticipated date of last follow up	31/08/2020
Actual Last follow-up date	31/08/2020
Anticipated target sample size (number of participants)	60
Actual target sample size (number of participants)	60
Recruitment status	Completed
Publication URL	

Secondary Ids **Issuing authority/Trial register**

STUDY DESIGN

Intervention assignment	Allocation to intervention	If randomised, describe how the allocation sequence was generated	Describe how the allocation sequence/code was concealed from the person allocating the participants to the intervention arms	Masking	If masking / blinding was used
Parallel: different	Randomised	Simple randomization	Sealed opaque envelopes	Masking/blinding used	Care giver/Provider,Outcome

groups receive different interventions at same time during study		using a randomization table created by a computer software program			Assessors,Participants
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INTERVENTIONS						
Intervention type	Intervention name	Dose	Duration	Intervention description	Group size	Nature of control
Control Group	Control Group	Group C: patients received 50 ml normal saline over a period of 20 minutes.	20 minutes	The women were randomized to 2 groups: C (Control group) and K (Ketamine group) using random number tables. The assigned treatments were written on cards and sealed in secure opaque envelopes numbered in sequence. On the scheduled time of operation, the head nurse (who was not part of the study) opened each envelope just before surgery, prepared the infusion solution and handled it to the anesthesiologist who was blinded to the solution. He was then determined for collecting perioperative data. Group C: patients received 50 ml normal saline over a period of 20 minutes.	30	Placebo
Experimental Group	Ketamine Group	Group K: patients received 0.4 mg/kg ketamine diluted in 50 ml normal saline over 20 min	20 minutes	The women were randomized to 2 groups: C (Control group) and K (Ketamine group) using random number tables. The assigned treatments were written on cards and sealed in secure opaque envelopes numbered in sequence. On the scheduled time of operation, the head nurse (who was not part of the study) opened each envelope just before surgery, prepared the infusion solution and handled it to the anesthesiologist who was blinded to the solution. He was then determined for collecting perioperative data. Group K: patients received 0.4 mg/kg ketamine diluted in 50 ml normal saline over 20 min	30	

ELIGIBILITY CRITERIA					
List inclusion criteria	List exclusion criteria	Age Category	Minimum age	Maximum age	Gender
18 years or older, physical status ASA I&II, with up to 12-week gestation, submitted to manual intrauterine aspiration for incomplete or retained abortion, participated in this randomized, double blind study.	patients with infected abortion or with psychiatric disorder on chronic medical treatment. Also, patients with pulmonary, hepatorenal, neuromuscular diseases body mass index over 30 kg/m2, usage of sedative drugs or substance abuse, any contraindications to regional anesthesia and finally emergency curettage for massive bleeding or hemodynamic instability	Adolescent: 13 Year-18 Year,Adult: 19 Year-44 Year,Middle Aged: 45 Year(s)-64 Year(s)	18 Year(s)	60 Year(s)	Female

ETHICS APPROVAL			
Has the study received appropriate ethics committee approval	Date the study will be submitted for approval	Date of approval	Name of the ethics committee
Yes		10/07/2019	Research Ethics Committee REC
Ethics Committee Address			
Street address	City	Postal code	Country
Abbasia	Cairo	11591	Egypt

OUTCOMES		
Type of outcome	Outcome	Timepoint(s) at which outcome measured
Primary Outcome	Our primary outcome is mood changes which were assessed preoperatively and 2 h postoperatively with POMS-A to determine if there were differences in mood state that could be attributed to the interventional drug infused.	preoperatively and 2 h postoperatively
Secondary Outcome	Secondary outcomes were: 1. Mean blood pressure and heart rate were measured preoperatively then every 5 min till end of the operation. Postoperatively, mean blood pressure, heart rate, were recorded every 30 minutes for 2 hours in PACU 2. Total dose of ketamine infused. 3. The duration of surgery in minutes. 4. Presence of psychedelic phenomenon [10] intraoperatively (during infusion) and/or postoperatively. It is a temporary altered state of consciousness that might be induced by ketamine infusion. The subjective phenomenon that might be reported included one or more of the following: perceptual disorders, a sense of detachment from their bodies	preoperatively and 2 h postoperatively

(dissociation), a sense of relaxation or well-being. Hallucinations, if occurred would be treated with injecting 2 mg intravenous midazolam. 5. Presence of intraoperative (during infusion) and/or postoperative other side effects as headache & diplopia 6. Presence of intraoperative (during infusion) and/or postoperative nausea and vomiting (PONV) which was rated on a 4-point scale (0=no PONV, 1=Mild nausea, 2=Severe nausea, 3=Vomiting). If PONV scale was 2 or more, ondansetron 4mg was given intravenously. 7. The patient satisfaction was assessed postoperatively at the 2nd hour. Patient satisfaction were rated on a scale of 1 to 4 (1=perfect, 2=good, 3=moderate, 4=bad). 8. Assessment of postoperative pain was done with the aid of visual analogue scale (VAS) in which patients were requested to estimate their pain on vertical VAS 0–10 cm where (0) is marked as no pain and (10) is marked as the worst pain ever felt. [11]. This was recorded postoperatively at specific timings: every 30 minutes for 2 hours postoperatively. 30 mg ketorolac was given intravenously if VAS score was > or equal to 4 at any of the mentioned times (with a maximum total ketorolac dose of 60 mg). 9. Assessment of perioperative sedation level using Sedation scale using University of Michigan Sedation Scale (UMSS) [12] The UMSS as a measure of sedation during procedures. The UMSS is a simple observational tool that assesses the level of alertness on a five-point scale ranging from 1 (wide awake) to 5 (unrousable with deep stimulation). Table (1) It will be assessed intraoperatively till the 2nd postoperative hour; every 30 minutes.

RECRUITMENT CENTRES

Name of recruitment centre	Street address	City	Postal code	Country
Ain Shams University hospital	Abbaseya	Cairo		Egypt

FUNDING SOURCES

Name of source	Street address	City	Postal code	Country
Ashraf Nabil Raham Hasan Mohamed Abdulmohsen Abdulnaiem Ismaiel	Abbasiya	Cairo		Egypt

SPONSORS

Sponsor level	Name	Street address	City	Postal code	Country	Nature of sponsor
Primary Sponsor	Ain Shams University	Abbasiya	Cairo		Egypt	Hospital

COLLABORATORS

Name	Street address	City	Postal code	Country
Ashraf Nabil Saleh	5th Settlement	Cairo		Egypt
Raham Hasan Mostafa	Nasr City	Cairo		Egypt
Mohamed Abdulmohsen Abdulnaiem Ismaiel	Heliopolis	Cairo		Egypt

CONTACT PEOPLE

Role	Name	Email	Phone	Street address
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Cairo		Egypt	Lecturer of Anesthesia Ain Shams University	
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City	Postal code	Country	Position/Affiliation	
Cairo		Egypt	Lecturer of Anesthesia Ain Shams University	

REPORTING

Share IPD	Description	Additional Document Types	Sharing Time Frame	Key Access Criteria
Yes	Excel Sheet	Statistical Analysis Plan	Twelve months	Only journal editors to whom manuscript will be applied to
URL	Results Available	Results Summary	Result Posting Date	First Journal Publication Date

Not Available	No			
Result Upload 1:	Result Upload 2:	Result Upload 3:	Result Upload 4:	Result Upload 5:
Results URL Hyperlinks	Link To Protocol			
Result URL Hyperlinks				

Changes to trial information					
Section Name	Field Name	Date	Reason	Old Value	Updated Value
Eligibility	Age group	16/07/2019	Correction to include minimum age of 18 years	Adult: 19 Year-44 Year, Middle Aged: 45 Year(s)-64 Year(s)	Adolescent: 13 Year-18 Year, Adult: 19 Year-44 Year, Middle Aged: 45 Year(s)-64 Year(s)
Section Name	Field Name	Date	Reason	Old Value	Updated Value
Funding Source	FundingSources List	16/07/2019	As requestd by reviewers		Ashraf Nabil Raham Hasan Mohamed Abdulmohsen Abdulnaiem Ismaiel, Abbasiya, Cairo, , Egypt, Self Funded,
Section Name	Field Name	Date	Reason	Old Value	Updated Value
Collaborators	Collaborators List	16/07/2019	As requested by reviewers		Ashraf Nabil Saleh, 5th Settlement, Cairo, , Egypt
Section Name	Field Name	Date	Reason	Old Value	Updated Value
Collaborators	Collaborators List	16/07/2019	As requested by reviewers		Raham Hasan Mostafa, Nasr City, Cairo, , Egypt
Section Name	Field Name	Date	Reason	Old Value	Updated Value
Collaborators	Collaborators List	16/07/2019	As requested by reviewers		Mohamed Abdulmohsen Abdulnaiem Ismaiel, Heliopolis, Cairo, , Egypt
Section Name	Field Name	Date	Reason	Old Value	Updated Value
Reporting	Plan to share IPD	16/07/2019	As requested by reviewers	No	Yes
Section Name	Field Name	Date	Reason	Old Value	Updated Value
Reporting	IPD description	16/07/2019	As requested by reviewers		Excel Sheet
Section Name	Field Name	Date	Reason	Old Value	Updated Value
Reporting	IPD-Sharing time frame	16/07/2019	As requested by reviewers		Twelve months
Section Name	Field Name	Date	Reason	Old Value	Updated Value
Reporting	Key access criteria	16/07/2019	As requested by reviewers		Only journal editors to whom manuscript will be applied to
Section Name	Field Name	Date	Reason	Old Value	Updated Value
Reporting	IPD URL	16/07/2019	As requested by reviewers		Not Available
Section Name	Field Name	Date	Reason	Old Value	Updated Value
Reporting	Study protocol document	16/07/2019	As requested by reviewers		Statistical Analysis Plan
Section Name	Field Name	Date	Reason	Old Value	Updated Value
Trial Information	Anticipated date of last follow up	31/08/2020	Study completed	30 Sep 2019	31 Aug 2020
Section Name	Field Name	Date	Reason	Old Value	Updated Value
Trial Information	Completion date	31/08/2020	Study completed	30 Sep 2019	31 Aug 2020
Section Name	Field Name	Date	Reason	Old Value	Updated Value
Trial Information	Recruitment status	31/08/2020	Study completed	Not yet recruiting	Completed