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Evaluation of preoperative anxiety and fear of anesthesia using Apais score

Submission date	Recruitment status	[_] Prospectively registered
15/02/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/02/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/09/2018	Surgery	

Plain English summary of protocol

Background and study aims
Patients often feel anxiety prior to undergoing surgery. The reason for the anxiety can be both anesthesia used to numb the pain and the actual surgery. The preoperative anxiety that patients have can cause side effects. It is important for the reasons of anxiety to help them in future operations. The aim of this study is to investigate the preoperative patient anxiety and patients fear of anesthesia.

Who can participate?
Adults aged 18 to 95 who are scheduled to undergo elective surgery.

What does the study involve?
Participants are asked to fill out a short questionnaire at the anesthesia clinic about their feelings of anxiety prior to undergoing anesthesia. They are asked if they had received anesthesia before, if they have surgical briefing, and the cause of their anxiety.

What are the possible benefits and risks of participating?
The potential benefit is we can decrease participants anxiety with our interviews. There are no side effects of participating to our study.

Where is the study run from?
Ahi Evran University Medical Faculty (Turkey)

When is the study starting and how long is it expected to run for?
February 2016 to July 2017

Who is funding the study?
Ahi Evran University Medical Faculty (Turkey)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
study no:2010-05/04

Study information

Scientific Title
Evaluation of preoperative anxiety and fear of anesthesia using the Amsterdam preoperative anxiety and information scale score: a prospective cohort stud

Study objectives
The aim of this study is to investigate how the patient's age, gender, the operation, surgical briefing, type of anesthesia recommended for the operation ahead, patient's prior anesthesia experience affect the patient's anxieties regarding anesthesia and surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Ahi Evran University on 27/04/2016, ref: 2016-05/04

Study design
Observational cross sectional cohort study

Primary study design

Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Preoperative anxiety and patients' fear of anesthesia

Interventions
Interviews with the patients are performed when they came to anesthesia clinic for preoperative examination, under the supervision of a specialist anesthetist.

For the study, The Amsterdam Preoperative Anxiety and Information Scale (APAIS), which comprises 6 statements, is used. The answers are evaluated in two scales; the anxiety score and the desire for information score. Anxiety score was obtained by calculating the total scores assigned to the expressions " I am worried about the anesthesic", "The anesthesic is on my mind continually", "I am worried about the procedure", "The procedure is on my mind continually", to measure the patient's level of anxiety regarding the anesthesia and surgery. Desire for information score is obtained by calculating the total scores assigned to the expressions "I would like to know as much as possible about the anesthesic " and "I would like to know as much as possible about the procedure “to measure the patient's level of desire for information regarding the anesthesia and surgery. Higher scores indicate higher levels of anxiety and desire for information. Answers to the statements were evaluated with Likert Scale. (1-Not at all… ,5-Extremely).

In addition, participants are asked whether they had received anesthesia due to any reason, if so, the type of anesthesia, and whether they received surgical briefing. Which anesthetic method recommended to the patient for the surgery they will undergo in the preoperative anesthesia clinic is recorded. Then, participants are asked about the cause of their anxiety regarding the anesthesia.

Intervention Type
Biological/Vaccine

Primary outcome measure
1. Demographics is measured using the patient notes at the preoperative anesthesia visit
2. Type of anaesthesia patient notes is measured using at the preoperative anesthesia visit
3. Prior experience with anaesthesia patient interviews is measured using at the preoperative anesthesia visit
4. Anxiety regarding anaesthesia is measured using APAIS (Amsterdam preoperative anxiety and information scale) at the preoperative anesthesia visit.

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
20/02/2016

Completion date
20/07/2017

Eligibility

Key inclusion criteria
1. ASA I-III
2. Adult patients who are scheduled to undergo elective surgery in our hospital
3. Adequate language skills for the interview were included in our study
4. 18-95 (all adults)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
95 Years

Sex
Both

Target number of participants
600

Key exclusion criteria
1. Pediatric patients
2. Patients who did not give consent
3. Patients with mental retardation
4. Alzheimer's disease
5. Dementia or psychiatric disorders
6. Emergency and ASA-IV patients

Date of first enrolment
28/05/2016

Date of final enrolment
20/05/2017

Locations

Countries of recruitment
Türkiye

Study participating centre
Ahi Evran University Medical Faculty
Department of Anesthesiology and Intensive Care Medicine
Kirsehir
Türkiye
40100

Sponsor information

Organisation
Ahi Evran University Medical Faculty

Sponsor details
Department of Anesthesiology and Intensive Care Medicine
Bağbaşı Mahallesi
Şht. Sahir Kurutluoğlu Cd.
Merkez
Kirsehir
Türkiye
40100

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05rrfpt58

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Ahi Evran University Medical Faculty clinical investigations

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal. Additional documents will not be available.

Intention to publish date
20/07/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Ipek S. Edipoglu at dripeks@yahoo.com.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/09/2018		Yes	No