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The effect of anxiety before surgery on recovery from anesthesia

Submission date
14/11/2020

Recruitment status
No longer recruiting

Registration date
18/11/2020

Overall study status
Completed

Last Edited
17/11/2020

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Patients in hospital who are about to undergo surgery tend to be nervous and anxious. The aim of this study is to compare the psychological effects of preoperative anxiety on anaesthesia recovery in patients undergoing varicose great saphenous vein surgery under general anesthesia.

Who can participate?
Patients between the ages of 18 and 65 years with varicose great saphenous vein undergoing general anesthesia and elective surgery in Shanghai East Hospital.

What does the study involve?
The participants are interviewed when they come to the anesthesia clinic for a preoperative examination under the instruction of an anesthesiologist. The participants answer questions about their anxiety regarding the anesthesia and surgery. The researchers also record characteristics including gender, age, height, weight, degree, and history of general anesthesia surgery.

What are the possible benefits and risks of participating?
Participating may benefit patients in the future. Participants may need to undergo more physical examinations, communicate with the doctor frequently, or receive hospital care. This may take more time and effort.

Where is the study run from?
Tongji University School of Medicine (China)

When is the study starting and how long is it expected to run for?
May 2019 to February 2020

Who is funding the study?
Shanghai East Hospital (China)

Who is the main contact?
Hui Wang
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
2020-005453-24

Protocol serial number
2019 (067)

Study information

Scientific Title
The midbrain ventral tegmental area is essential for delayed awakening from general anesthesia of anxiety state: in vivo and in vitro

Study objectives
Preoperative anxiety state can induce adverse outcomes in surgical patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/05/2019, Shanghai East Hospital Medical Ethics Committee (150 Jimo Road, Pudong New Area, Shanghai, China; +86 (0)21 61569829; qxw1123@126.com), ref: not applicable

Study design
Single-centre observational cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients with varicose great saphenous vein who received general anesthesia and elective surgery

Interventions
The participants are interviewed when they come to the anesthesia clinic for preoperative examination under the instruction of an anesthesiologist. The participants are asked to sit on a chair and answer the questions of the Amsterdam Preoperative Anxiety and Information Scale (APAIS). Anxiety scores are evaluated by calculating the scores for the six statements of the APAIS. Anxiety score is obtained by calculating the total scores assigned to the expressions " I am worried about the anesthetic", "The anesthetic is on my mind continually", "I would like to know as much as possible about the anesthetic", "I am worried about the procedure", "The procedure is on my mind continually", "I would like to know as much as possible about the procedure" to measure the patient's level of anxiety regarding the anesthesia and surgery. Higher scores suggest a higher grade of anxiety. The researchers also record demographic characteristics, including gender, age, height, weight, degree, and history of general anesthesia surgery. The study visit and postoperative extubation procedure are performed by two different anesthesiologists.

Intervention Type
Other

Primary outcome(s)
Extubation time, defined as the time between drug withdrawal and the time at which a BIS greater than or equal to 85 was achieved and the tube could be removed

Key secondary outcome(s))
1. Post-anesthesia anesthesia recovery measured using Alderte score every 15 min in the post-anesthesia recovery room (PACU)
2. Postoperative pain visual analog scale (VAS) scores at 6 h, 12 h, and 24 h
3. Postoperative nausea and vomiting VAS scores at 6 h, 12 h, and 24 h
4. Postoperative restlessness measured using sedative and agitation scale (SAS) at 5, 10, 15 and 20 min after entering the PACU
5. Chills measured using postoperative shiver score at 5, 10, 15 and 20 min after entering the PACU
6. Operation length, measured as the time interval from the initiation to the end of surgery
7. Anesthesia length, measured as the time interval from the initiation of anesthesia to the end of surgery
8. Length of hospital stay, measured as discharge date minus admission day plus one

Completion date
25/02/2020

Eligibility

Key inclusion criteria
18-65-year-old patients with varicose great saphenous vein who received general anesthesia and elective surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
82

Key exclusion criteria
1. Psychiatric disorders
2. Alzheimer's disease
3. Mental retardation
4. Cardiopulmonary severe dysfunction
5. Liver and kidney dysfunction
6. History of drug or alcohol abuse
7. ASA III-IV patients

Date of first enrolment
01/08/2019

Date of final enrolment
25/02/2020

Locations

Countries of recruitment
China

Study participating centre
Tongji University School of Medicine
Department of Anesthesiology
East Hospital
150 Jimo Road
Pudong New Area
Shanghai
China
200120

Sponsor information

Organisation
Tongji University

ROR
https://ror.org/03rc6as71

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Shanghai East Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Hui Wang (huihuismile@126.com).

IPD sharing plan summary
Available on request