

The effect of anxiety before surgery on recovery from anesthesia

Submission date 14/11/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/11/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/11/2020	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name

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Additional identifiers

EudraCT/CTIS number

2020-005453-24

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

11/05/2019

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

82

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

Sponsor details

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qxw1123@126.com

Sponsor type

University/education

Website

<http://www.easthospital.cn/>

ROR

<https://ror.org/03rc6as71>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Shanghai East Hospital

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/03/2021

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