

# The effect of anxiety before surgery on recovery from anesthesia

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

Miss Hui Wang

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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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**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