

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of effects of Music and Midazolam on the anxiety levels during fibroptic bronchoscopy

#### Protocol summary

##### Summary

Our aim in this study is to compare the effects of Music and Midazolam on the anxiety levels during fibroptic bronchoscopy. In a randomized, single blinded uni-central study without Placebo, 60 male and female in or out-patients in Emam Reza hospital, Tabriz, with minimum age of 15 years would be involved during a 6 months period. Inclusion criterion is having indication for fibroptic bronchoscopy. Exclusion criteria are: patients with mental, hearing or speaking disorders; emergency bronchoscopy; patients with attention disorders; patients with brain defects; patients whom their mother tongue is not persian or azary; patients younger than 15 years old; patients under treatment with corticosteroids in systemic or inhale forms. Subjects would be randomly assigned in Midazolam or Music groups. Individuals in the first group will receive Midazolam 2mg intravenously 5 minutes before the initiation of the bronchoscopy and for subjects in the second group Music will be played using a headphone from 10 minutes before the bronchoscopy till the end of the bronchoscopy. Blood Nor-epinephrine, Epinephrine Cortisol levels, anxiety levels, blood oxygen saturation level and heart rate will be checked and recorded before (basal level) and after the bronchoscopy.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201012035287N2**

Registration date: **2012-01-10, 1390/10/20**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-01-10, 1390/10/20

#### Registrant information

##### Name

Akbar Sharifi

##### Name of organization / entity

Tabriz Medical University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1337 5449

##### Email address

asharifi@tbzmed.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Tabriz University of Medical Sciences

#### Expected recruitment start date

2011-09-11, 1390/06/20

#### Expected recruitment end date

2012-03-09, 1390/12/19

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of effects of Music and Midazolam on the anxiety levels during fibroptic bronchoscopy

#### Public title

Music or Midazolam ?! A new relaxation method during bronchoscopy

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

Inclusion criterion: having indication for fibroptic bronchoscopy. Exclusion criteria: patients with mental, hearing or speaking disorders; emergency bronchoscopy; patients with attention disorders; patients with brain

defects; patients whom their mother tongue is not persian or azary; patients younger than 15 years old; patients under treatment with corticosteroids in systemic or inhale forms and patients with adrenal insufficiency.

#### **Age**

From **15 years** old to **149 years** old

#### **Gender**

Male

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **60**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Single blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics Committee of Tabriz Medical University

###### **Street address**

Vice chancellor for research, Tabriz Medical University,  
Daneshgah square

###### **City**

Tabriz

###### **Postal code**

##### **Approval date**

2011-02-28, 1389/12/09

##### **Ethics committee reference number**

8961

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Bronchoscopy induced anxiety

##### **ICD-10 code**

F43.0

##### **ICD-10 code description**

Acute stress reaction

### **Primary outcomes**

#### **1**

##### **Description**

Heart rate

##### **Timepoint**

Before and after bronchoscopy

##### **Method of measurement**

Using continuous cardiac monitoring

#### **2**

##### **Description**

Anxiety level

##### **Timepoint**

Before and after bronchoscopy

##### **Method of measurement**

Using Beck's anxiety questionnaire

#### **3**

##### **Description**

Blood Oxygen saturation

##### **Timepoint**

Before and after bronchoscopy

##### **Method of measurement**

Using pulseoximetry

#### **4**

##### **Description**

Blood Cortisol level

##### **Timepoint**

Before and after bronchoscopy

##### **Method of measurement**

Using blood sampling and laboratory testing

#### **5**

##### **Description**

Blood nor-epinephrine level

##### **Timepoint**

Before and after bronchoscopy

##### **Method of measurement**

Using blood sampling and laboratory testing

#### **6**

##### **Description**

Blood epinephrine level

##### **Timepoint**

Before and after bronchoscopy

##### **Method of measurement**

Using blood sampling and laboratory testing

### **Secondary outcomes**

empty

### **Intervention groups**

## 1

### Description

Injection of 2mg midazolam IV 5 minutes before bronchoscopy for group Midazolam

### Category

Treatment - Drugs

## 2

### Description

Playing music by a headphone 10 minutes before the initiation of bronchoscopy for group Music

### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Reza hospital

##### Full name of responsible person

Akbar Sharifi

##### Street address

Emam Reza hospital, Golgasht street

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz Medical University

##### Full name of responsible person

Alireza Ostad Rahimi

##### Street address

Vice chancellor for research, Tabriz Medical University, Daneshgah square

##### City

Tabriz

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Tabriz Medical University

#### Proportion provided by this source

100

#### Public or private sector

*empty*

#### Domestic or foreign origin

*empty*

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Tabriz Medical University

#### Full name of responsible person

Akbar Sharifi

#### Position

Subspecialist in pulmonary diseases, Assistant professor

#### Other areas of specialty/work

#### Street address

Bronchoscopy ward, Emam Reza hospital, Golgasht street

#### City

Tabriz

#### Postal code

#### Phone

+98 41 1336 4901

#### Fax

#### Email

ak.sharif@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tabriz Medical University

#### Full name of responsible person

Akbar Sharifi

#### Position

Subspecialist in pulmonary diseases, assistant professor

#### Other areas of specialty/work

#### Street address

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Tabriz Medical University

#### Full name of responsible person

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Subspecialist in pulmonary diseases, assistant professor

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*