

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, Golgast 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

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 updating data

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

Fax

Email

Web page address

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