

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

The effect of Distraction on Anxiety and Tolerance in patient undergoing Bronchoscopy admitted to Emam Ali Hospital in Zahedan , 2015

Protocol summary

Summary

Participants were randomly divided into intervention (30 patients) and control (30 patients) groups. At first, obtaining written informed consent from participants is a signature on a form. After that, through interview and review of patient record, personal demographics, individual health status and diseases was completed. Before the procedure, level of blood pressure (systolic and diastolic) and Pulse rate (per minute), through "mobile vital signs monitor", was recorded for all subjects by the second investigator who was unaware of the intervention and control groups. Also, the visual analog scale (VAS) and the anxiety questionnaire (The Spielberger State-Trait Anxiety Inventory (STAI)) through interview and patient self-report were filled. Patient, at the Bronchoscopy room, was on the bed with supine position so that the bed under the patient's head was 30 degrees angle. In the intervention group, at the same time, the patient was put on headphones to listen to music and nature images on the screen via video projector, ten minutes before the start to the end of Bronchoscopy, was broadcast. During Bronchoscopy for both groups, blood pressure and pulse rate were recorded every three minutes (after the third, sixth and ninth). After the end of Bronchoscopy, The third part of the questionnaire was completed by the researcher for all participants in the test. Finally, after the patient calm and before leave the Bronchoscopy room, patient tolerance was recorded by visual analog scale (VAS) for tolerance indices during bronchoscopy. The anxiety questionnaire that was delivered to the patient by a second researcher was filled with interviews and self-reports by patients. Also blood pressure and pulse rate were recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042922001N1**

Registration date: **2015-07-24, 1394/05/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-24, 1394/05/02

Registrant information

Name

Shahla Soleymani

Name of organization / entity

Zahedan University Of Medical Science, School of Nursing & Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 54 3344 2482

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soleymanish2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research & Technology, Zahedan University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-09-21, 1394/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Distraction on Anxiety and Tolerance in

patient undergoing Bronchoscopy admitted to Emam Ali Hospital in Zahedan , 2015

Public title

The effect of Distraction on Anxiety and Tolerance in patient undergoing Bronchoscopy admitted to Emam Ali Hospital in Zahedan , 2015

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: participants should: be between 20 to 60 years old; have the ability of speaking and Persian language understanding; be conscious and health on their hearings and visions; be undergoing bronchoscopy for the first time. Exclusion criteria: have background of severe psychological problems; have a severe symptoms (pain, cough and dyspnea) caused by respiratory diseases (asthma, lung cancer, etc); use the strong sedative or narcotic before bronchoscopy; be under treatment with corticosteroids (systemic or inhalation); have the emergency indication bronchoscopy.

Age

From **20 years** old to **60 years** old

Gender

Both

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

Zahedan University of Medical Sciences

Street address

Pardis Zahedan Univercity Of Medical Science, Doctor Hesabi Square

City

Zahedan

Postal code

9816743463

Approval date

2015-05-31, 1394/03/10

Ethics committee reference number

IR.ZAUMS.REC.1394.85

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

43.0F

ICD-10 code description

Acute stress reaction

Primary outcomes

1

Description

Anxiety

Timepoint

Before the start Bronchoscopy, ten minute after finishing Bronchoscopy.

Method of measurement

The Spielberger State-Trait Anxiety Inventory (STAI)

2

Description

Tolerance

Timepoint

Before the start Bronchoscopy, ten minute after finishing Bronchoscopy.

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Systolic and Diastolic Blood Pressure

Timepoint

Before start Bronchoscopy, every three minutes (after the third, sixth and ninth) during bronchoscopy, ten minutes after finishing bronchoscopy.

Method of measurement

Mobile Vital Signs Monitoring Device

2

Description

Pulse Rate

Timepoint

Before start bronchoscopy, every three minutes (after the third, sixth and ninth) during bronchoscopy, ten minutes after finishing bronchoscopy.

Method of measurement

Mobile Vital Signs Monitoring Device

Intervention groups

1

Description

In the intervention group, at the same time, the patient was put on headphones to listen to music and nature images on the screen via video projector, ten minutes before the start to the end of Bronchoscopy, was broadcast.

Category

Other

2

Description

The control group received usual care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ebne Abitaleb Hospita

Full name of responsible person

Nezar Ali Muolai

Street address

Ali Ebne Abitaleb Hospital, khalije Fars Blvd

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Science

Full name of responsible person

Hoshang Rafighdost

Street address

Pardis Zahedan Univercity Of Medical Science, Doctor Hesabi Square,

City

Zahedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan University of Medical Science

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

Zahedan University of Medical Science, School of Nursing & Midwifery

Full name of responsible person

Shahla Soleymani

Position

Master Student Critical Care Nursing

Other areas of specialty/work

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Full name of responsible person

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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