Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Univercity Of Medical Science, School of Nursing & Midwifery

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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,
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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
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Full name of responsible person
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Master Student Critical Care Nursing
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Person responsible for updating data

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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