

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Clinical trial to compare the effectiveness of nursing interventions and lack of nursing interventions on anxiety in patients undergoing endoscopy

Protocol summary

Summary

This experimental study aimed to evaluate the effect of nursing intervention on anxiety in patients undergoing endoscopy and it will be performed with participation of 80 patients undergoing endoscopy referred to Ayatollah Taleghani hospital of Urmia in 2014. Samples will allocated by simple random sampling to either experimental (n=40) or control groups (n= 40). So that endoscopy candidates of even days will be placed in the control group and patients of odd days in the intervention group. Inclusion criteria include: Having order for upper gastrointestinal endoscopy, aged 18 to 60 years and without history of previous endoscopy. The use of hypnotics and sedatives, having severe pain due to the nature of the disease (eg, cancer), opioid material addiction or strong analgesics are exclusion criteria. The experimental group will receive nursing interventions include training preparation before the procedure, explaining about all the steps before, during and after endoscopy, the patient's awareness, deep breathing training and positive mental reinforcement in patient about endoscopy and endoscopy day, while the control group will not receive any intervention. Anxiety level will be measured in both groups before intervention and on endoscopy day (immediately before the procedure).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031817059N1**

Registration date: **2014-06-27, 1393/04/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-27, 1393/04/06

Registrant information

Name

Masoume Hemmati Maslakpak

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 1365 9031

Email address

hemmati_m@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Urmia University of Medical Sciences.

Expected recruitment start date

2014-06-21, 1393/03/31

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial to compare the effectiveness of nursing interventions and lack of nursing interventions on anxiety in patients undergoing endoscopy

Public title

Effect of nursing interventions on anxiety in patients undergoing endoscopy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Having order for upper gastrointestinal endoscopy, aged 18 to 60 years, without history of previous endoscopy, without emergency endoscopy order and Iranian nationality. Exclusion criteria: The use of hypnotics and sedatives, having severe pain due to the nature of the disease (eg, cancer), opioid material addiction or strong analgesics.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not 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 Urmia University of Medical Sciences

Street address

Jahad square, University of Medical Sciences, Urmia

City

Urmia

Postal code

575611-5111

Approval date

2014-05-20, 1393/02/30

Ethics committee reference number

umsu.rec.1393.69

Health conditions studied

1

Description of health condition studied

anxiety

ICD-10 code

F41.1

ICD-10 code description

Anxiety that is generalized and persistent but not restricted to, or even strongly predominating in, any particular environmental circumstances (i.e. it is

Primary outcomes

1

Description

Anxiety

Timepoint

Before endoscopy and half hour before endoscopy in procedure day

Method of measurement

Spielburger Anxiety questionnaire

Secondary outcomes

1

Description

Systolic and diastolic blood pressure, pulse rate

Timepoint

Before endoscopy and half an hour before endoscopy in procedure day

Method of measurement

Using mercury sphygmomanometer and radial pulse by nurse

Intervention groups

1

Description

Intervention 2: Lack of nursing intervention before of procedure

Category

Behavior

2

Description

Intervention 1: Nursing intervention: Training preparation before the procedure involves fasting for 8 hours before the procedure , how to use a local anesthetic throat to eliminate Gag reflex before the procedure , observe the lateral position left during the procedure , the possibility of using certain drugs such as atropine to reduce secretions and glucagon to relax the muscles , showing the endoscopy setting , explain all procedures before, during and after endoscopy , the patient's awareness about the benefits and risks, giving the patient the opportunity to express feelings and questions, Responding to questions posed by the patient , deep breathing training, patients positive mental reinforcement to support them.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Taleghani hospital of Urmia

Full name of responsible person

Samira Orujlu

Street address

Nursing and Midwifery Faculty, 11 km Sero road,
Urmia

City

Urmia

Samira Orujlu

Position

Msc. Faculty member

Other areas of specialty/work

Street address

Nursing and Midwifery Faculty, 11 km Sero road,
Urmia

City

Urmia

Postal code

575611-5111

Phone

+98 44 1275 4961

Fax

+98 44 1275 2378

Email

samira_orojlo@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Urmia University of
Medical Sciences

Full name of responsible person

Iraj Mohebbi

Street address

Jahad square, Urmia University of medical sciences

City

Urmia

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Urmia University of Medical
Sciences

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Urmia University of Medical Sciences

Full name of responsible person

Person responsible for updating data

Contact

Name of organization / entity

Urmia University of Medical Sciences

Full name of responsible person

Samira Orujlu

Position

Msc. Faculty member

Other areas of specialty/work

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Fax

+98 44 1275 2378

Email

samira_orojlo@yahoo.com

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