

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effectiveness of Implementing Nursing Consultation on "Anxiety and Satisfaction of Patients Undergoing GI Endoscopy

Protocol summary

Summary

The objective of this study is to determine the effects of nursing consultation on the anxiety level of the patient before gastrointestinal endoscopy and their satisfaction about it. In this quasi- experimental study in Amirmomenin hospital of Arak, 120 patients are scheduled to undergo upper GI Endoscopy. The patients are randomly allocated to experimental or control group. The patients in the experimental group receive intervention of nursing consultation lasted 30 minutes about endoscopy a day before the procedure, while control group does not receive any intervention. Anxiety level (recorded by spielburger questionnaire) and vital signs are measured in both groups before intervention and on the endoscopy day (immediately before the procedure). During the endoscopy, the cooperation of the patients and their satisfaction are measured by VAS, 6 hours after endoscopy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103256103N1**

Registration date: **2011-10-22, 1390/07/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-10-22, 1390/07/30

Registrant information

Name

Olia Bakhshayeshi

Name of organization / entity

Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2010-12-21, 1389/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of Implementing Nursing Consultation on "Anxiety and Satisfaction of Patients Undergoing GI Endoscopy

Public title

The effectiveness of Implementing Nursing Consultation on "Anxiety and Satisfaction of Patients Undergoing GI Endoscopy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Having order of upper GI Endoscopy at least one day before the procedure, Age between 18 and 80 years old, Ability to speak and understanding Persian language, no problem to see the VAS, no previous endoscopy, no order of emergency Endoscopy, no History of psychological disease or anxiety disorder, no consumption of opiate or sedative drugs, no severe pain due to nature of disease, no addiction to opium or

narcotics, no hypertension or using anti hypertensive drugs Exclusion criteria: canceling the Endoscopy due to any reason except for patient's anxiety, no willingness to participate in the study

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Central building of TUMS, Ghods street, Keshavarz Blvd., Tehran

City

Tehran

Postal code

6514- 151684

Approval date

2010-08-10, 1389/05/19

Ethics committee reference number

620/130/89/5

Health conditions studied

1

Description of health condition studied

Uper GI Endoscopy

ICD-10 code

K20, K31

ICD-10 code description

Diseases of Oesophagus, Stomach and Duodenum

Primary outcomes

1

Description

Blood presure

Timepoint

One day before Endoscopy(before consultation) and immediately before Endoscopy

Method of measurement

indicator

2

Description

anxiety

Timepoint

One day before Endoscopy(before consultation) and immediately before Endoscopy

Method of measurement

spielberger questionair

3

Description

Cooperation

Timepoint

WHILE Endoscopy

Method of measurement

Visual Analog scale

4

Description

pulse rate

Timepoint

One day before Endoscopy(before consultation) and immediately before Endoscopy

Method of measurement

by researcher

5

Description

respiratory rate

Timepoint

One day before Endoscopy (before consultation) and immediately before Endoscopy

Method of measurement

by researcher

Secondary outcomes

1

Description

Patient's satisfaction

Timepoint

6 hours after Endoscopy

Method of measurement

Visual Analog Scale

Intervention groups

1

Description

Intervention group: consultation for half an hour one day before Endoscopy. This consultation is performed by researcher for out-patients in hospital or patient home (at tendency of patient) and for inpatients on the bed of patient. This consultation is nursing consultation and do not need to advanced techniques of psicologia. This consultation is including instruction about needing preparation pre Endoscopy (such as diet, drugs,...), explanation about stages pre(instruction necessary preparations), in(explanation about What will happen during Endoscopy)) and after(explanation about the probable problems that will meet after Endoscopy) Endoscopy. It increase patient knowledge about Endoscopy and its advantages and probable risks and allow to patient that express his sensations and questions and answering the questions of patient.

Category

Treatment - Other

2

Description

Control group: No intervention other than routine care

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Endoscopy Unit Of Amiralmomenin Hospital Of Arak

Full name of responsible person

Dr Alireza Nikbakht Nasrabadi

Street address

Amiralmomenin Hospital, University Town, Emam Khomeyni Boulevard, Emam Khomeyni Sq., Arak City, Iran

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences and Health Services

Full name of responsible person

Abbas Hooshmand Bahabadi

Street address

Faculty of Nursing and Midwifery, Prime of eastward Nosrat, Tohid Square, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences and Health Services

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

Tehran University of Medical Sciences and Health Services

Full name of responsible person

Olia Bakhshayeshi

Position

Student of Master Degree of Medical_ Surgical Nursing

Other areas of specialty/work

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Next to Allameh Tabatabai library, End of Jomhoori Street, Mahallat

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences and Health Services

Full name of responsible person

Aliraza Nikbakht Nasrabadi

Position

PhD of Nursing

Other areas of specialty/work

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Tehran University of Medical Sciences and Health Services

Full name of responsible person

Olia Bakhshayeshi

Position

Student of Master Degree of Medical_ Surgical Nursing

Other areas of specialty/work**Street address**

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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*