Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 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 Amiralmomenin 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 endocscopy, 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 Univercity of Medical Sciences

Country

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/ɔ

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 consultatoin 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 consoltation is nursing cosultation and do not need to advanced techniques of psicologia. This consoltation 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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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences and Health Services

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Aliraza Nikbakht Nasrabadi

Position
PhD of Nursing

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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