

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6692 2700

###### Email address

zparsa@tums.ac.ir

###### 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

##### Street address

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

##### City

Mahallat

##### Postal code

3781684916

##### Phone

+98 32 51255

##### Fax

+98 86 6325 0524

##### Email

roya\_b1383

##### 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

##### Street address

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

**City**

Tehran

**Postal code**

6459

**Phone**

+98 21 6692 2700

**Fax**

+98 21 6690 4252

**Email**

nikbakht@tums.ac.ir

**Web page address****City**

Mahallat

**Postal code**

3781684916

**Phone**

+98 86 6325 1255

**Fax**

+98 86 6325 0524

**Email**

roya\_b1383

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences and Health Services

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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*