

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Comparison the effect of the application of Benson relaxation technique and supplemental oxygen therapy and their combination on anxiety and chemotherapy-induced nausea and vomiting in patients with gastric cancer

Protocol summary

Study aim

Determining and comparing the effect of the application of Benson relaxation technique and supplemental oxygen therapy and their combination on anxiety and chemotherapy-induced nausea and vomiting in patients with gastric cancer in Imam Khomeini Teaching Hospital in Urmia in 2020

Design

four-group clinical trial, 2 * 2 factorial design, convenient sampling, sample size will include 100 patients, block allocation.

Settings and conduct

One week before the start of the first course of chemotherapy, patients in all four groups complete the Nausea and Vomiting Index and the Self Anxiety Scale. Then patients in groups A and B perform Benson relaxation technique at home twice a day for 10 to 15 minutes. Patients in groups A and C receive 5 liters of oxygen per minute through the nasal cannula during chemotherapy. The severity of nausea and vomiting in all four groups will be assessed and compared immediately after chemotherapy, 24 hours, 2, 3, 4, and 5 days after chemotherapy session.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with gastric cancer based on medical records Being in the first period of receiving injectable chemotherapy drugs The use of chemotherapy drugs with side effects of nausea and vomiting, mild to severe Hospitalization for chemotherapy No concomitant radiotherapy Willingness to participate in the study Ability to communicate Having a minimum literacy
Exclusion criteria: Not wanting to continue to participate in the project

Intervention groups

The implementation of Benson relaxation technique, supplemental oxygen therapy and a combination of

Benson relaxation technique with supplemental oxygen therapy. The control group will receive routine care.

Main outcome variables

Nausea and vomiting; The anxiety.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180808040742N3**

Registration date: **2020-12-08, 1399/09/18**

Registration timing: **prospective**

Last update: **2020-12-08, 1399/09/18**

Update count: **0**

Registration date

2020-12-08, 1399/09/18

Registrant information

Name

Yaser Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3336 7978

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-03-21, 1400/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison the effect of the application of Benson relaxation technique and supplemental oxygen therapy and their combination on anxiety and chemotherapy-induced nausea and vomiting in patients with gastric cancer

Public title
Comparison of Benson relaxation technique and supplemental oxygen therapy and their combination on anxiety and chemotherapy-induced nausea and vomiting in patients with gastric cancer

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with gastric cancer based on medical records
 Being in the first period of receiving injectable chemotherapy drugs
 The use of chemotherapy drugs with side effects of nausea and vomiting, mild to severe
 Hospitalization for chemotherapy
 Lack of known mental illness including severe depression (based on patient medical history records)
 No brain malignancy
 No chronic obstructive pulmonary disease
 No drugs and alcohol
 No concomitant radiotherapy
 No inner ear disorder
 Willingness to participate in the study
 Ability to communicate
 Having a minimum literacy
Exclusion criteria:
 Not wanting to continue to participate in the project
 Go to travel

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 100

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, block allocation will be done and based on the factors affecting nausea and vomiting (type of chemotherapy drug and patient gender). For each study group, two male and female blocks and 4 blocks in terms of nauseating severity of chemotherapy drugs (high, moderate, low, minimum possible amount) will be considered. Accordingly, there will be 8 arms in each group. The first patient from each block will be randomly assigned to one of four groups.

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

Vice-chancellor for research of Urmia University of Medical Sciences, Resalat Blvd

City

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West Azarbaijan

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5714783734

Approval date

2020-07-19, 1399/04/29

Ethics committee reference number

IR.UMSU.REC.1399.205

Health conditions studied

1

Description of health condition studied

Gastric cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety

Timepoint

One week before the start of the first course of chemotherapy, immediately, 24 hours, 2, 3, 4 and 5 days after the chemotherapy session

Method of measurement

Self Anxiety Scale

2

Description

Nausea and Vomiting

Timepoint

One week before the start of the first course of chemotherapy, immediately, 24 hours, 2, 3, 4 and 5 days

after the chemotherapy session
Method of measurement
Rhodes Index of Nausea and Vomiting

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A: The intervention includes Benson relaxation technique and complementary oxygen therapy.

Category

Treatment - Other

2

Description

Intervention group B: The intervention is Benson relaxation technique.

Category

Treatment - Other

3

Description

Intervention group C: The intervention is complementary oxygen therapy.

Category

Treatment - Other

4

Description

Control group: Routine cares

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini Hospital in Urmia

Full name of responsible person

Omid Mirzamohammadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

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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

Oroumia University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Yaser moradi

Position

Assistant Professor, Urmia Nursing and Midwifery faculty

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Student of Master of Science in Nursing

Latest degree

Bachelor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available