Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Oct 2026

A Clinical trial to study the effect of information prescription in reducing relaps among patients with inflammatory bowel disease

Protocol summary

Summary

The aim of this study was to evaluate the effect of treatment with prescription information, to inflammatory bowel disease.The sample size was 160 patients with inflammatory bowel disease who were referred to a hospital clinic of Imam Reza (AS) Tabriz, during a visit of the first Persian date Mordad 1394 to 1395 is the first pole of the year.Random sampling will be carried out.The study will be a blinded.Blind will also evaluate the data.Evidence-based information regarding the current situation of the patient to his doctor prescribes,Prepared by an expert librarian And after assessments and simplify it in terms of intelligibility For patients in a printed format in writing to the intervention group and the oral explanation provided.But groups control only receive oral information in accordance with the usual procedure.The implications of this study are:The effect of therapeutic intervention in reducing relapses, the effect of therapeutic intervention in health care costs;The effect of therapeutic intervention in the frequency of complications of hypochondriasis after the release of health information, the effect of therapeutic intervention in the reduction of drug and dosage, the effect of therapeutic intervention in inflammatory bowel disease, quality of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510137612N2**
Registration date: **2016-05-24, 1395/03/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-05-24, 1395/03/04

Registrant information

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Name of organization / entity
Medical Science of Tabriz University
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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences - Research Department

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Clinical trial to study the effect of information prescription in reducing relaps among patients with inflammatory bowel disease

Public title

The Effect of information therapy prescribed by physician to reduce relaps in patients with inflammatory bowel disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients with inflammatory bowel

disease; literate (minimum cycle) or at least the carer to be literate. Consciousness,no acceess to information other than intervention such as family members. Age between 18 to 85 years, consent to participate in the study.Exclusion criteria: Prior knowledge and informed: Patients who already have other sources of information other than the version information Such as having access to a doctor in the family, or close friends in that case, patients should be excluded;Lack of awareness;Chronic digestive diseases other than that for which the drugs.

Age
From **18 years** old to **85 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sciences

Street address
Tabriz, GOLGASHT, University Avenue, University of Medical Sciences

City
Tabriz

Postal code
5166615739

Approval date
2015-07-06, 1394/04/15

Ethics committee reference number
TBZMED.REC.1394.355

Health conditions studied

1

Description of health condition studied
Inflammatory bowel disease

ICD-10 code
K50

ICD-10 code description
Crohn disease [regional enteritis]

2

Description of health condition studied
Inflammatory bowel disease

ICD-10 code
K51

ICD-10 code description
Ulcerative colitis

Primary outcomes

1

Description
Reduction of relapses

Timepoint
Two and four months after intervention

Method of measurement
Phone calls and questionnaires

Secondary outcomes

1

Description
medical expenses

Timepoint
Two and four months after intervention

Method of measurement
Call-questionnaire

2

Description
Frequency of complications Hypochondrias

Timepoint
Two and four months after intervention

Method of measurement
Call-questionnaire

3

Description
Change in the number of drugs and dose of intake

Timepoint
Two and four months after intervention

Method of measurement
Call-questionnaire

4

Description
Quality of life

Timepoint
Two and four months after intervention

Method of measurement
Call-questionnaire

Intervention groups

1

Description
In this study, the type of intervention in the form of a written copy of the information prescribed by a doctor.Patients in the intervention group in addition to the usual information that is given to patients. Treatment with oral prescription information to librarians about the information they receive. Information content includes information about inflammatory bowel disease, medications, tests, symptoms, exercise and self-care is health.The control group did not receive written information and oral librarian.

Category
Prevention

2

Description
Patients in control group only received verbal information typically provided by your doctor, and the doctor does not receive health information.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Dr. Mohammad Hossein Somi
Street address
Tabriz, GOLGASHT, Imam Reza Hospital
City
Tabriz

2

Recruitment center
Name of recruitment center
Sheikh Alrys clinic affiliated with the University of Medical Sciences
Full name of responsible person
Dr. Mohammad Hossein Somi
Street address
Tabriz, Liberty Avenue, not far from the GOLGASHT, Avicenna Clinic
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences Research Council
Full name of responsible person
Dr. Mohammad Reza Rashidi, Deputy Director for Research
Street address
Tabriz, GOLGASHT, University Avenue, University of Medical Sciences
City
Tabriz

Grant name

Grant code / Reference number

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

Title of funding source
Tabriz University of Medical Sciences Research Council

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
Tabriz University of Medical Sciences
Full name of responsible person
Parisa Akbari Aykdh Lu
Position
A graduate student in Library and Information Science Medicine
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
dr. Vahideh Zarea Gavgani
Position

Associate professor of medical library and information sciences

Other areas of specialty/work

Street address

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Position

A graduate student in Library and Information Science Medicine

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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