

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Evaluation of the effect of melatonin on clinical, biochemical parameters and quality of life in Ulcerative colitis patients

Protocol summary

Study aim

The aim of present study is to determine whether adding melatonin tablet to treatment regimen in patients with UC (ulcerative colitis) will improve clinical, biochemical parameters and quality of life

Design

Design of the study is a triple-blind, placebo-controlled, randomized control single center clinical trial. Patients with age more than 20 years old with UC will be enrolled the study. Patients whom are not desired to enroll the study will be excluded. In this research, 40 eligible patients with UC compatible with inclusion criteria were chosen. patients were randomly divided into two control and intervention groups by Microsoft Excel software. and a code was allocated to each one of them.

Settings and conduct

This study is conducted as placebo controlled triple blinded randomized clinical trial in taleqani hospital participants, researcher & statistical data analyzer all has been blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: uc Age more than 20 years old
Exclusion criteria: History of confirmed hypersensitivity reaction to melatonin or any parts of formulation eGFR less than 30 ml/min/1.73m² Liver failure (child pugh B, C) Pregnancy & lactation Uncontrolled seizure & untreated major depressive disorder Concurrent use of fluvoxamine , nifedipine & NSAID

Intervention groups

Intervention group (melatonin supplement): UC patients compatible with inclusion/exclusion criteria on UC treatment regimens administrated with 3 mg oral melatonin supplement daily for 3 mouths. Control group (melatonin placebo): UC patients patients compatible with inclusion/exclusion criteria on UC treatment regimens administrated with 3 mg oral melatonin placebo daily for 3 mouths.

Main outcome variables

Change in hs-CRP, Hemoglobin& Fecal calprotectin :

improvement of quality of life with SF36 index & clinical symptoms with Simple clinical colitis activity index (SCCAI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121021011192N9**

Registration date: **2019-12-03, 1398/09/12**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-03, 1398/09/12**

Update count: **0**

Registration date

2019-12-03, 1398/09/12

Registrant information

Name

Mohammad Abbasinazari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of melatonin on clinical, biochemical parameters and quality of life in Ulcerative colitis patients

Public title

The effect of melatonin in Ulcerative colitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

UC disease in patients with more than 20 years old

Exclusion criteria:

History of confirmed hypersensitivity reaction to melatonin or any parts of formulation eGFR less than 30 ml/min/1.73m² Liver failure (child pugh B, C) Pregnancy & lactation Uncontrolled seizure & untreated major depressive disorder Concurrent use of fluvoxamine , nifedipine & non steroidal anti inflammatory drugs(NSAID)

Age

From **20 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data and Safety Monitoring Board

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with Microsoft Excel software

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants, principle investigator, healthcare providers (Physicians, nurses) who care for participants during the trial, data collectors and outcome assessors all are blinded by providing placebo melatonin in same size, shape color, odor and package with real melatonin tablet which organized just by one responsible co-researcher has no involvement in running study.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee school of pharmacy and nursing and midwifery- shahid Beheshti university of medica

Street address

School of Pharmacy, Nyayesh junction, Valiasr street,Tehran

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Postal code

1985717413

Approval date

2019-09-24, 1398/07/02

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1398.158

Health conditions studied**1****Description of health condition studied**

Ulcerative colitis

ICD-10 code

K51

ICD-10 code description

Ulcerative colitis

Primary outcomes**1****Description**

Change in Fecal calprotectin level

Timepoint

Before intervention and 90 days after initiation of daily use of melatonin

Method of measurement

Lab kits

2**Description**

change in high sensitivity CRP serum level

Timepoint

Before intervention and 90 days after initiation of daily use of melatonin

Method of measurement

Lab kits

3**Description**

Change in Hemoglobin level

Timepoint

Before intervention and 90 days after initiation of daily use of melatonin

Method of measurement

Lab kits

4**Description**

improvement of clinical symptoms of uc

Timepoint

Before intervention and 90 days after initiation of daily use of melatonin

Method of measurement

Interview with patients based on Simple clinical colitis activity index questionnaire

5**Description**

improvement of quality of life

Timepoint

Before intervention and 90 days after initiation of daily use of melatonin

Method of measurement

Interview with patients based on SF36 questionnaire

Secondary outcomes**1****Description**

Record of Adverse drug reactions

Timepoint

During intervention

Method of measurement

Interview with patients

Intervention groups**1****Description**

Intervention group: Addition of melatonin tablet orally 3 mg/d to UC regimen for 3 months

Category

Treatment - Drugs

2**Description**

Control group: Addition of melatonin placebo tablet orally 3 mg/d to UC regimen for 3 months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

بیمارستان طالقانی

Full name of responsible person

محمد عباسی نظری

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

roja qobadi ghadikolaei

Position

board certified clinical pharmacist

Latest degree

Subspecialist

Other areas of specialty/work

Medical Pharmacy

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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

Undecided - It is not yet known if there will be 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