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

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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
hange 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
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Sponsors / Funding sources

1

Sponsor
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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
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roja qobadi ghadikolaei
Position
board certified clinical pharmacist

Latest degree
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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