Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Assessing the effect of Matricaria Chamomilla on sleep quality in elderly people admitted to Nursing Home care

Protocol summary

Study aim
determining the effect of Matricaria Chamomilla on sleep quality in elderly people admitted to Nursing Home care

Design
This is a randomized, double blind, cross over clinical trial. It is conducted through pre-test and post-test in chamomilla and placebo groups. The samples will allocate in two groups by randomized blocks, the sample size will be 60 that allocated in two groups of 30 in intervention and placebo groups

Settings and conduct
This research will focus on sleep quality in elderly people in nursing home in Rasht city, in order to determine the sleep quality. This is a double blind research . Both elderly people and researcher are not aware of the content.

Participants/Inclusion and exclusion criteria
1) willingness about participating in the research and filling up the consent form 2) having the age of 60 and more 3)being a resident of nursing care home 4)the ability of answering the questionarie 5)no allergic history of using the Chamomilla 6)no constant use of Chamomilla extract or sodden in last 6 months exclusion criteria: 1) interrupting the use of Chamomilla end of the research 2) catching a disease during the research that prevent the samples using the chamomilla 3) incidents of allergic reaction of using chamomilla 4)no tendency of continuing the research 5)egress of research in order of dying or moving to another center

Intervention groups
the patients will randomly be assigned to 2 groups: 1)30 elderly people in the Chamomilla group 2) 30 elderly people in the placebo group consider to the cross over method, the elderly people will use the capsules in a cycle of 28 days, after a week wash out the groups will change, that's how the chamomilla in the first cycle will use placebo and the placebo group in the first cycle will use chamomilla in the second cycle.

Main outcome variables
sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20080901001174N12**
Registration date: **2019-04-11, 1398/01/22**
Registration timing: **prospective**

Last update: **2019-04-11, 1398/01/22**
Update count: **0**

Registration date
2019-04-11, 1398/01/22

Registrant information

Name
Atefeh Ghanbari

Name of organization / entity
Guilan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 13780509

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-21, 1398/02/01

Expected recruitment end date
2019-06-22, 1398/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessing the effect of Matricaria Chamomilla on sleep quality in elderly people admitted to Nursing Home care

Public title
Effect of Matricaria Chamomilla on sleep quality in elderly people

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
willingness about participating in research and filling up the consent form having the age of 60 and more being a resident of nursing care home having the ability of answering the questions

Exclusion criteria:
No allergic history of using Chamomilla No constant use of Chamomilla extract or sodden in last 6 months

Age
From **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
This is a randomized, double blind, cross over clinical trial. It is conducted through pre-test and post-test in chamomilla and placebo groups. The samples will allocate in two groups by simple randomized blocks. The samples size is 55 people With confidence level of 95% and test strength of 80%. But consider to 10% of samples drop out, the samples actual size will be 60 that allocated in two groups of 30 in intervention and placebo groups. The ANCOVA and independent t-test will use to estimate the relationship between sleep quality in elderly people and personal characteristic. For analyzing the samples data will use descriptive and deductive estimation that consist of ANCOVA, independent t-test, paired t-test, Mannwhitney test, Willcoxon with 21th version of SPSS soft ware. In order to equal the personal characteristics the cross over method will be use

Blinding (investigator's opinion)
Double blinded

Blinding description
The drugman will give the samples the placebo and chamomilla capsules with marking and checklist. the samples and the researcher are not aware of the content of the capsules. The use of drugs will be checked by the drugman, the chamomilla and placebo capsules that will be eaten by the samples twice a day will have the same shape, color and flavor

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی گیلان

Street address
Guilan university of medical sciences, Namjoo street

City
Rasht

Province
Guilan

Postal code
4193833697

Approval date
2019-02-23, 1397/12/04

Ethics committee reference number
IR.GUMS.REC.1397.464

Health conditions studied

1

Description of health condition studied
sleep quality and elderly

ICD-10 code
F51.12

ICD-10 code description
Insufficient sleep syndrome

Primary outcomes

1

Description
sleep quality score

Timepoint
before starting the intervention and 28, 35 and after the intervention

Method of measurement
to determine the sleep quality score we will use Pittsburg sleep quality index.

2

Description
sleep status ferquency

Timepoint
before starting the intervention and 28, 35 and after the intervention

Method of measurement

to determine the sleep status frequency we will use Pittsburg sleep quality index.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 30 elderly people who are the resident of Rasht nursing care home are including in this group. They receive Chamomilla capsules twice a day, once after lunch and once after dinner every day. The 200mg Chamomilla capsules were made by Booali pharmaceutical company. After one week wash out they will receive placebo capsules that contain Saccharin twice a day for 28 days.
Category
Treatment - Drugs

2

Description
Control group: 30 elderly people who are the resident of Rasht nursing care home are including in this group. They receive placebo capsules twice a day, once after lunch and once after dinner every day. The placebo capsules were made by Booali pharmaceutical company. After one week wash out they will receive Chamomilla capsules twice a day for 28 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Nursing care home in Rasht
Full name of responsible person
Atefeh Ghanbari
Street address
Faculty of Nursing and Midwifery, Daneshjo street, shahid Beheshti highway, Rasht
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
atefeh ghanbari
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Deputy of research building, shahid Siadati Ave, Namjoo Ave, Rasht
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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
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Atefeh Ghanbari
Position
associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
main and total data

When the data will become available and for how long
starting in 2019

To whom data/document is available
universities and scientific institutions

Under which criteria data/document could be used
consider to citing the articles

From where data/document is obtainable
executor of the proposal

What processes are involved for a request to access data/document
contact with proposal executor and make ethical agreement

Comments
without comment