Clinical Trial Protocol
Iranian Registry of Clinical Trials
27 Apr 2020

The effect of Matricaria chamomilla extract on sleep quality in elderly people admitted to nursing homes of Isfahan in 2014

Protocol summary

Summary
Sleep is one of the basic human needs. Research suggests that sleep quality is diminished with increasing age and the elderly are susceptible to damage caused by poor quality of sleep. Pharmacotherapy for the treatment of sleep disorders, which in many cases may cause adverse effects in the elderly. Research has shown that chamomile extract may be effective on sleep quality. Therefore, in this quasi-experimental clinical trial to determine the effect of MC extract on sleep quality in elderly people admitted to nursing homes takes place, aged 80, after informed consent, are divided into two groups. Intervention group twice daily after lunch and after dinner, chamomile extract 400 mg capsules and the control group received no intervention will be. Sleep quality in elderly people by participating in both pre- and post-intervention questionnaires Pittsburgh Sleep Quality Standard will be measured and will be compared.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT2013102015080N1
Registration date: 2014-05-23, 1393/03/02
Registration timing: registered_while_recruiting

Last update: empty
Update count: 0
Registration date 2014-05-23, 1393/03/02

Registrant information
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Mehrdad Abdullahzadeh
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source
Khorasgan (Isfahan) Branch, Islamic Azad University

Expected recruitment start date
2014-05-14, 1393/02/24
Expected recruitment end date
2014-06-14, 1393/03/24
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Matricaria chamomilla extract on sleep quality in elderly people admitted to nursing homes of Isfahan in 2014

Public title
The effect of chamomile on sleep in elderly
Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: tend to participate in the study and give consent to do so; having more than 60 years of age; having mental health; the non-occurrence of whatever specific diseases of liver, kidney, asthma, cancer and mental disorders are diagnosed; stay in one of the nursing homes studied; ability to answer questions; lack of sensitivity to chamomile or any of its ingredients; lack of continuous consumption of tea or chamomile extract during the last six months; capability than chamomile capsules orally; lack of sleep-related illnesses, such as obstructive sleep apnea or restless legs syndrome; the lack of dependence on any drug, analgesics, antidepressants, sleeping, alcohol and the lack of heparin, warfarin, and aspirin (due to drug interactions with chamomile extract). Exclusion criteria: stopping chamomile by subject, for whatever reason before the end of the intervention period; drug against the patient dose; catching whatever disease during the study period, which led to a ban by the oral administration of MC; indicate any allergic reaction to the MC during the research; lack of willingness to cooperate in the
investigation; withdrawal from the study for reasons such as death, illness, or transferred to other centers.

**Age**  
From 60 years old

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**  
No information

**Sample size**  
Target sample size: 80

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
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  
Isfahan University of Medical Sciences  
Street address  
Isfahan University of Medical Sciences  
City  
Isfahan  
Postal code

2  
**Approval date**  
2014-05-14, 1393/02/24  
**Ethics committee reference number**  
23810403922004

**Health conditions studied**

1  
**Description of health condition studied**  
Insomnia  
**ICD-10 code**  
G47.0  
**ICD-10 code description**  
Disorders of initiating and maintaining sleep [insomnias]

**Primary outcomes**

1  
**Description**  
Quality of sleep  
**Timepoint**  
Pre-intervention and post-intervention  
**Method of measurement**  
Pittsburgh Sleep Quality Index

**Secondary outcomes**  
empty

**Intervention groups**

1  
**Description**  
Chamomile extract of 400 mg twice daily  
**Category**  
Treatment - Drugs

2  
**Description**  
No action  
**Category**  
N/A

**Recruitment centers**

1  
**Recruitment center**  
Name of recruitment center  
Nursing homes related to IsfahanWelfare  
**Full name of responsible person**  
**Street address**  
**City**  
Isfshsn

**Sponsors / Funding sources**

1  
**Sponsor**  
Name of organization / entity  
Khorasgan (Isfahan) Branch , Islamic Azad University , Isfahan , Iran  
**Full name of responsible person**  
Dr. payam najafi  
**Street address**  
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**City**  
Isfahan  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Khorasgan (Isfahan) Branch , Islamic Azad University , Isfahan , Iran  
**Proportion provided by this source**
Person responsible for general inquiries

Contact
Name of organization / entity
Khorasgan (Isfahan) Branch , Islamic Azad University , Isfahan , Iran
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Student
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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