Comparison of the efficacy of Valerian root extract and oral Diazepam on pre-operative anxiety before Orthopedic Surgeries

Protocol summary

Summary
The purpose of this study is determining the effects of essence of Valeriana officinalis roots in anxiety of patients in contrast to diazepam oral drop. In this study the researcher will go to the Emama Ali Hospital in Borojerd, the night before the surgery. Amongst the candidate patients of orthopedic surgery, the conscious testimonials were taken from the legitimate patients. Patients should have following conditions in order to entering to study: Patients should be aware, being capable at reading and writing at the lowest level, passing first and second grade of USA anesthesia assembly (ASA). Not having any records of mental and neurotic problems. Not using narcotics. Not being alcoholic. Patients who are extremely anxious (the grade of obvious anxiety be more than 64 or the grade of covert anxiety be more than 62) or using anti anxiety or tranquilizer medicines, should be eliminated from the study. After taking testimonial, patients will categorized randomly in 3 groups that each group has 16 people in it. One group will take 5 mg of diazepam oral drop; one group will take sedamin capsules of 350 mg (valeriana officinalis) and the last group will take placebo. Before taking medicine, the obvious and the covert anxious of the patient and his vital signs and demo graphic information will be recorded by spiel Berger’s questionnaire. The next morning this information will be gathered in surgery room. The gathered information at the night before the surgery will be compared with the information that had been gathered in surgery room and then they will be analyzed and examines from statistical point of view.

General information

Acronym

IRCT registration information
IRCT registration number: IRCT2013041112978N1
Registration date: 2014-06-24, 1393/04/03

Registration timing: retrospective

Last update: empty
Update count: 0
Registration date
2014-06-24, 1393/04/03

Registrant information
Name
Javad Shahinfar
Name of organization / entity
North Khorasan University of Medical Science
Country
Iran (Islamic Republic of)
Phone
+98 58 4224 7124
Email address
javad.shahinfar@nkums.ac.ir

Recruitment status
Recruitment complete
Funding source
North Khorasan University of Medical Sciences

Expected recruitment start date
2012-03-19, 1390/12/29
Expected recruitment end date
2013-03-19, 1391/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the efficacy of Valerian root extract and oral Diazepam on pre-operative anxiety before Orthopedic Surgeries

Public title
Comparison of the efficacy of Valerian root extract and oral Diazepam on pre-operative anxiety before Orthopedic Surgeries

Purpose
Supportive

Inclusion/Exclusion criteria
Criterions of entering to the study: complete awareness, being capable at reading and writing at the lowest level, passing first and second grade of USA anesthesia assembly (ASA). Not having any records of mental and neurotic problems. Not using narcotics. Not being alcoholic.
Criterions of exiting from study: being extremely anxious (the grade of obvious anxiety be more than 64 or the grade of covert anxiety be more than 62). Using anti anxiety or tranquilizer medicines.

Age
From 15 years old to 60 years old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 48

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Secondary design features

Secondary Ids
empty

Ethics committees

Ethics committee

Name of ethics committee
Ethics Council of North Khorasan University of Medical Sciences

Street address
North Khorasan University of Medical Sciences, Bojnourd, North Khorasan, Iran

City
Bojnourd

Postal code

Approval date
2012-09-22, 1391/07/01

Ethics committee reference number
8

Health conditions studied

1

Description of health condition studied
Pre-operative Anxiety

ICD-10 code
F41.9

ICD-10 code description
Anxiety disorder unspecified

Primary outcomes

1

Description
Anxiety

Timepoint
The night before surgery in Ward(before Drug or Placebo use) and the morning of surgery in Operation Room

Method of measurement
The State-Trait Anxiety Inventory(STAI)

Secondary outcomes

1

Description
Pulse Rate

Timepoint
The night before surgery in Ward(before Drug or Placebo use) and the morning of surgery in Operation Room

Method of measurement
Computation of Pulse Rate in one minute

2

Description
Blood Pressure

Timepoint
The night before surgery in Ward(before Drug or Placebo use) and the morning of surgery in operation room

Method of measurement
Stethoscope and Handheld Manometer

3

Description
Respiratory Rate

Timepoint
The night before surgery in Ward(before Drug or Placebo use) and the morning of surgery in operation room

Method of measurement
Computation of Respiratory Rate in one minute

Intervention groups

1

Description
First Intervention group: Sedamin, Capsule, 530mg, once, The night before of surgery
Category: Prevention

2
Description: Control group: Starch, Placebo Capsule, once, The night before of surgery
Category: Placebo

3
Description: secondary Intervention group: Diazepam, Tablet, 5mg, once, The night before of surgery
Category: Prevention

Recruitment centers

1
Recruitment center
Name of recruitment center: Emam Ali hospital
Full name of responsible person: Zahra Rostami
Street address: Emam Ali hospital, Sahriar St, Bojnourd
City: Bojnourd

Sponsors / Funding sources

1
Sponsor
Name of organization / entity: North Khorasan University of Medical Sciences
Full name of responsible person: Dr Golshan
Street address: North Khorasan University of Medical Sciences, Bojnourd, North Khorasan, Iran
City: Bojnourd
Grant name
Grant code / Reference number: empty
Is the source of funding the same sponsor organization/entity?: Yes
Title of funding source: North Khorasan University of Medical Sciences
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: empty
Type of organization providing the funding: empty

Person responsible for general inquiries

Contact
Name of organization / entity: North Khorasan University of Medical Sciences
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Other areas of specialty/work: empty
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Person responsible for scientific inquiries

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Fax: +98 58 4229 7095
Email: jshahinfar@yahoo.com
Web page address: empty

Person responsible for updating data

Contact
Name of organization / entity: North Khorasan University of Medical Sciences
Full name of responsible person: Saeed Shojaei
Position: B.Sc. of Anesthesia
Other areas of specialty/work
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Phone
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Web page address

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