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
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Name of organization / entity
North Khorasan University of Medical Science
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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

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

**Other design features**

**Secondary Ids**
empty

**Ethics committees**

**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
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

Person responsible for general inquiries

Contact
Name of organization / entity
North Khorasan University of Medical Sciences
Full name of responsible person
Dr Javad Shahinfar
Position
Anesthesia
Other areas of specialty/work
Street address
School of Nursing and Midwifery, Shahriar st, Bojnourd
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Bojnourd
Postal code

Person responsible for scientific inquiries

Contact
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North Khorasan University of Medical Sciences
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Person responsible for updating data

Contact
Name of organization / entity
North Khorasan University of Medical Sciences
Full name of responsible person
Saeed Shojaei
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B.Sc. of Anesthesia
Other areas of specialty/work
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  School of Nursing and Midwifery, Shahriar st, Bojnourd
City
  Bojnourd
Postal code
Phone
Fax
Email
  Shojaei_Saeed@yahoo.com
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