Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Effect of Vitamin B6 versus propranolol in patients with neuroleptic - induced Akathisia : A randomized-double blind study

Protocol summary

Summary

Objectives: The purpose of this study is to evaluate the efficacy of vitamin B6 in the treatment of acute neuroleptic-induced akathisia Design:a 5-day double-blind, randomized trial. 51 adult inpatients who meet the DSM- IV-TR criteria for akathisia participate in the trial. Setting snd conduct: Patients who have a Baseline Barnes Akathisia Scale (BAS) score of at least 2 will be allocated into three groups. 17 patients will receive vitamin B6 1200 mg/day and 17 participants will receive vitamin B6 600 mg per day and remaining 17 participants will receive propranolol 40 mg per day. Patients were assessed by a psychiatrist at baseline and each day up to 5 days after the medication started and he will be blind about grouping.medications will be prescribebed in similar formulations. Akathisia severity will be assessed by Barnes Akathisia Scale (BAS) . Participants: 51 adult patients who have a Baseline Barnes Akathisia Scale (BAS) score of at least 2 will be eligible . patients who have received betablocker or their anticholinergic has been changed will be excluded Intervention: Vitamine B6 versus placebo duration of intervention: 5 days Main outcome measures: patients' score in Barnes Akathisia Scale(BAS)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111042935N6**
Registration date: **2012-02-18, 1390/11/29**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-02-18, 1390/11/29

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Kurdistan University of Medical Sciences

Expected recruitment start date

2012-02-20, 1390/12/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Vitamin B6 versus propranolol in patients with neuroleptic -induced Akathisia : A randomized-double blind study

Public title

Vitamin B6 in the treatment of akathisia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:being hospitalized ;receiving neuroleptic medication; Presence of akathisia based on DSM-IV criteria; Baseline Barnes Akathisia Scale (BAS)

score of at least 2 Exclusion criteria: any hepatic or renal disease; change in the dose of anticholinergic drugs within 5 days before the trial; receiving any beta-blocker medication during the study

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **51**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kurdistan University of Medical Sciences

Street address
No 1, Pasdaran Blvd.Kurdistan University of Medical Sciences, Sanandaj

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Postal code

Approval date
2011-10-15, 1390/07/23

Ethics committee reference number
20183

Health conditions studied

1

Description of health condition studied
medication-induced acute akathisia

ICD-10 code
G25

ICD-10 code description
Other extrapyramidal and movement disorders

Primary outcomes

1

Description
severity of akathisia

Timepoint
baseline and every day up to 5 days

Method of measurement
Barnes Akathisia Scale (BAS)

Secondary outcomes

empty

Intervention groups

1

Description
vitamin B6 600 mg per day for 5 days

Category
Treatment - Drugs

2

Description
vitamin B6 1200 mg per day for 5 days

Category
Treatment - Drugs

3

Description
propranolol 40 mg per day for 5 days

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Qods Hospital

Full name of responsible person
Narges Shams Alizadeh

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No2, Pasdaran Blvd., Qods Hospital, Sanandaj

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Sponsors / Funding sources

1

Sponsor

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Vice chancellor for research, Kurdistan University of Medical Sciences

Full name of responsible person
Dr Ataollah Heydari

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No1, Pasdaran Blvd, Kurdistan university of Medical Sciences, Deputy of research, Sanandaj
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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
Vice chancellor for research, Kurdistan 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
Type of organization providing the funding
empty

Person responsible for general inquiries

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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