Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of Curcumin on bone density loss and biochemical marker of bone turn over in patient with Spinal Cord Injury

Protocol summary

Summary

The aim of this study is to investigate the effects of Curcumin on bone loss and bone turnover markers in patients with Spinal Cord Injury (SCI) . The study was double-blind clinical trial on patients referred to the Neurosurgery clinic. Inclusion criteria: age equal to 18 years, trauma, recent SCI (less than 6 months), paraplegia or quadriplegia. Exclusion criteria: any secondary cause of osteoporosis such as metabolic or endocrine disease. The patients were divided randomly into two case and control. Patients in case group 100 mg / kg / day of Curcumin intravenously received for 6 month. All clinical examination and biochemical markers of bone turnover assaying and also densitometry measurements of patients at baseline and 6 months after the intervention were performed for all patients. Statistical analysis was performed end-to interpret result.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010225805N1**
Registration date: **2016-04-21, 1395/02/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-04-21, 1395/02/02

Registrant information

Name

Masoud Hatefi

Name of organization / entity

Ilam University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Ilam University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2015-11-21, 1394/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Curcumin on bone density loss and biochemical marker of bone turn over in patient with Spinal Cord Injury

Public title

Effect of Curcumin on Osteoprosis in patient with Spinal Cord Injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age equal to 18 years; trauma; recent SCI (less than 6 months); paraplegia or quadriplegia move engagement protocol spinal cord injury America Association (ASIA). Exclusion criteria: any secondary cause of osteoporosis such as metabolic or endocrine disease; osteogenesis imperfecta; tumors; chronic cardiovascular diseases; liver; anti-osteoporosis medications during the selection of patients; Alcoholism; pregnancy; chronic use of steroids; smoking; older than 70

Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **100**
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 Ilam University of Medical Sciences, Ilam, Iran
Street address
Ilam
City
Ilam
Postal code
Approval date
2015-09-23, 1394/07/01
Ethics committee reference number
ir.medilam.rec.1394.186

Health conditions studied

1

Description of health condition studied
spinal cord injury
ICD-10 code
T09.3
ICD-10 code description
Injury of spinal cord, level unspecified

Primary outcomes

1

Description
Bone Density of Total Hip
Timepoint
Before intervention and 6 month after intervetion
Method of measurement
Dansitometry Lab

2

Description
Bone Density of lumbar vertebral (L1-L4)
Timepoint
Before intervention and 6 month after intervetion
Method of measurement
Laboratory assay

3

Description
Bone Density of Femoral Neck
Timepoint
Before intervention and 6 month after intervetion
Method of measurement
Laboratory assay

4

Description
Bone Specific alkaline phsphatase
Timepoint
Before intervention , 3 month after intervention and 6 month after intervetion
Method of measurement
ElISA

5

Description
Propeptide amino-terminal of type I procollagen
Timepoint
Before intervention and 6 month after intervetion
Method of measurement
ElISA

6

Description
Osteoclacin
Timepoint
Before intervention and 6 month after intervetion
Method of measurement
ElISA

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Calcium Plus(Caspian Tamin co, Iran) 1000 mg daily for 6 months
Category

Treatment - Drugs

2

Description
Intervention group: Curcumin (Mina Laboratory co,Iran) 110 mg/kg daily for 6 months+ Calcium Plus 1000 mg daily for 6 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurosurgery Clinic of Imam Khomeini in Ilam city
Full name of responsible person
Masoud Hatefi
Street address
Neurosurgery Clinic, Imam Khomeini Hospital, Street 22 Bahman, Ilam city, Ilam, Iran.
City
Ilam

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Ilam University of Medical Sciences
Full name of responsible person
Dr Kourosh Sayhemiri
Street address
Ilam University of Medical Sciences, boulevard Research, Ban Ganjab, Ilam city, Ilam, Iran
City
Ilam
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 of Ilam 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

Contact
Name of organization / entity
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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