

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.

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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

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)

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 Osteoporosis 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 intervention

Method of measurement

Dansitometry Lab

2**Description**

Bone Density of lumbar vertebral (L1-L4)

Timepoint

Before intervention and 6 month after intervention

Method of measurement

Laboratory assay

3**Description**

Bone Density of Femoral Neck

Timepoint

Before intervention and 6 month after intervention

Method of measurement

Laboratory assay

4**Description**

Bone Specific alkaline phsphatase

Timepoint

Before intervention , 3 month after intervention and 6 month after intervention

Method of measurement

EIISA

5**Description**

Propeptide amino-terminal of type I procollagen

Timepoint

Before intervention and 6 month after intervention

Method of measurement

EIISA

6**Description**

Osteoclastin

Timepoint

Before intervention and 6 month after intervention

Method of measurement

EIISA

Secondary outcomes

empty

Intervention groups**1****Description**

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

Category

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

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Ilam University of Medical Sciences, boulevard
Research, Ban Ganjab, Ilam city, Ilam, Iran

City

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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 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**

Ilam University of Medical Sciences

Full name of responsible person

Dr Mohammad Reza Hafezi Ahmadi

Position

Pathologist

Other areas of specialty/work**Street address**

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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