

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy of Nasal Spray Calcitonin on Recurrence of Aggressive Central Giant Cell Granuloma

Protocol summary

Summary

The main objective of this randomised clinical trial is to compare the frequency of recurrence between patients who received nasal spray calcitonin after curettage of Central Giant Cell Granuloma and without it. A total of 24 patients with aggressive Central Giant Cell Granuloma (CGCG) will be selected. All examinations were performed by calibrated clinicians and gender, age, medical history, symptoms, lesion size and site, disease duration and form of treatment were recorded for all participants. Radiographic examination with cone beam computed tomography (CBCT) and panoramic radiograph was done for all patients. All patients were randomly assigned to one of two treatment groups; 2 weeks after the biopsies were taken. The case of first group (n = 12 with) underwent calcitonin 200 IU/day once a day for 3 months after the surgeries. conservative curettage surgical procedure was done for them. while placebo was treated by curettage of CGCGs and received a placebo once a day for 3 months after surgeries. Patients were followed up by a maxillofacial surgeon who did not participate in surgeries. None of the surgeons was aware about the research before and during the operations. Patients were blinded from the drugs which they received after surgeries. All patients were followed up for 5 years after operations. Recurrence lesions were documented by clinical and radiographical examinations and proved by histopathological evaluation.

General information

Acronym

CGCG

IRCT registration information

IRCT registration number: **IRCT2015011820711N1**

Registration date: **2015-02-21, 1393/12/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-21, 1393/12/02

Registrant information

Name

Sorena Fardisi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Medical University of Shiraz

Expected recruitment start date

2007-09-06, 1386/06/15

Expected recruitment end date

2009-04-03, 1388/01/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Nasal Spray Calcitonin on Recurrence of Aggressive Central Giant Cell Granuloma

Public title

Treatment of Aggressive Central Giant Cell Granuloma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: • clinical and histopathological diagnosis of aggressive CGCG based on accepted criteria established by Chuong et al; normal level of calcitonin and serum Parathyroid hormone (PTH) Patients; ; of both sexes between 13 to 30 year's old Patients who gave written informed consent Patients who were willing for evaluation in the follow up session; Primary size of the lesion should be more than 5 cm in CBCT; Exclusion Criteria: • Participants demonstrating a systemic disease which affects bone healing; brown tumor ; pregnancy ; recently corticosteroid therapy ; previous surgical intervention for CGCG or refused study enrollment and whom they could not continue the study for private or social reasons were excluded from the study sample.

Age

From **15 years** old to **30 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

ClinicalTrials.gov

Secondary trial Id

NCT02358304

Registration date

2015-01-16, 1393/10/26

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

st zand

City

shiraz

Postal code

Approval date

2007-07-20, 1386/04/29

Ethics committee reference number

91-01-03-5278

Health conditions studied

1

Description of health condition studied

central giant cell granuloma

ICD-10 code

k10.1

ICD-10 code description

Giant cell granuloma, central

Primary outcomes

1

Description

- Relief sign & symptom and clinical features [Time Frame: 5 years] [Designated as safety issue: Yes]

Timepoint

5 years

Method of measurement

Recurrence lesions were documented by clinical and radiographical examinations and proved by histopathological evaluation

Secondary outcomes

1

Description

- recurrence rate of CGCG [Time Frame: 5 years] [Designated as safety issue: Yes]

Timepoint

5 years]

Method of measurement

Recurrence lesions were documented by clinical and radiographical examinations and proved by histopathological evaluation

Intervention groups

1

Description

Active Comparator: a: Patients with aggressive CGCG Patients had been clinically with CGCG and confirmed by histopathological findings were selected for the study. Gender, age, medical history, symptoms, size, and site of the lesions, duration of disease were recorded. Local ethical committee approval was obtained before the trial started and all patients gave written informed consent. Patients were randomly divided into two groups. First group received nasal spray calcitonin 200 IU/ day for 3 months after surgical curettage was done.

Category

Treatment - Drugs

2

Description

Placebo Comparator: b; Patients with aggressive CGCG Patients had been clinically with CGCG and confirmed by histopathological findings were selected for the study. Gender, age, medical history, symptoms, size, and site of the lesions , duration of disease were recorded. Local ethical committee approval was obtained before the trial started and all patients gave written informed consent. Patients were randomly divided into two groups . second group received placebo after surgical curettage for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz University of Medical Sciences

Full name of responsible person

Reza Tabrizi, DMD

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Memarpour

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City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Assistant professor of Shiraz University of Medical Sciences, Shiraz University of Medical Sciences

Full name of responsible person

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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