Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 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 participant. 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 caseof first group (n =12 with) underwent calcitonin 200 IU/day ones 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 ones a day for 3 months after surgeries.. Patients were followed up by a maxillofacial surgeon who did not participated in surgeries.None of surgeons did not aware about the research before and during the operations.Patients were blinded from the drugs which they received after surgeries. All patients were follow 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
Shiraz Medical Univercity
Country
Iran (Islamic Republic of)
Phone
+98 71 3631 5241
Email address
fardisi@sums.ac.ir

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 etal; 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 fallow 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 Memarpoor

Street address
Ghasdasht st

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
Reza Tabrizi, DMD

Position
Assistant professor

Other areas of specialty/work

Street address
Ghasdasht ST.

City
Sshiraz

Postal code

Phone
+98 71 3631 2313

Fax

Email
tabmed@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Assistant professor of Shiraz University of Medical Sciences, Shiraz University of Medical Sciences

Full name of responsible person
Reza Tabrizi, DMD

Position
Assistant professor

Other areas of specialty/work

Street address
Ghasrdasht ST.

City
Shiraz

Postal code

Phone
+98 71 3631 2313

Fax

Email
tabmed@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Resident of maxillofacial surgery of Shiraz University of Medical Sciences

Full name of responsible person
Sorena Fardisi DMD

Position
Resident

Other areas of specialty/work

Street address

City
Shiraz

Postal code

Phone
+98 71 3631 2313
Fax
Email
fardisi@sums.ac.ir
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