

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of histomorphometric effects of risedronate gel (2%) on calvaria bone defects in rabbits

Protocol summary

Summary

Objective: Evaluation of histomorphometric effects of risedronate gel (2%) on reconstruction of calvaria bone defects in New Zealand white rabbit. Design: Randomized (randomized block design - with two groups of ten, case and control groups); double-blind (blinded for the subjects and evaluation committee); placebo-controlled. Sample size: Twenty male New Zealand rabbits with the same breed and weight. Inclusion criteria: Animals with same weight, age and gender; without disease. Exclusion criteria: Diagnosis of the disease. Method: Randomized clinical trial. Duration: Four & eight weeks. Setting and conduct: After giving anesthesia, we make two full thickness 8 millimeter defects in calvaria bones of each rabbit by using a Dask bur. In group 1, the right defect is filled with risedronate 2% gel and the left defect is empty. In group 2, right defect is filled with placebo gel and left defect remain empty. Then the area will be stitched. At the end of each month (for two consecutive months - month1 and month2) five rabbits will be euthanized and their calvaria bone will be removed for histomorphometric study, and samples will be sent to pathologist. Intervention: 1- Risedronate 2% gel; once, during surgery; localized in bone defect. 2-Placebo gel; once, during surgery; localized in bone defect. Primary outcome variables: The amount of bone filling; inflammation; osteoblasts; osteoclasts; foreign body reaction. Secondary outcome variables: Infection; presence of the disease.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081235636N1**

Registration date: **2017-08-21, 1396/05/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-08-21, 1396/05/30

Registrant information

Name

Shirin Marzoughi

Name of organization / entity

Islamic Azad University, Dental Tehran Branch

Country

Iran (Islamic Republic of)

Phone

+98 912 500 7698

Email address

shirin.marzoughi@gmail.com

Recruitment status

Recruitment complete

Funding source

Researcher

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-06-20, 1394/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of histomorphometric effects of risedronate gel (2%) on calvaria bone defects in rabbits

Public title

Evaluation of effect of risedronate on the process of bone formation in rabbit's skull

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Animals with same weight, age and gender; without disease. Exclusion criteria: Diagnosis of the disease.

Age

From **6 months** old to **7 months** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University, Dental
Tehran Branch

Street address

10th Neyestan St., Pasdaran Ave., Tehran, Iran.

City

Tehran

Postal code

19585175

Approval date

2014-06-20, 1393/03/30

Ethics committee reference number

24820

Health conditions studied

1

Description of health condition studied

Bone loss

ICD-10 code

K05

ICD-10 code description

Gingivitis and periodontal diseases

Primary outcomes

1

Description

The amount of bone filling

Timepoint

Four weeks after intervention, eight weeks after
intervention

Method of measurement

by microscopic observation

2

Description

Inflammation

Timepoint

Four weeks after intervention, eight weeks after
intervention

Method of measurement

by microscopic observation

3

Description

Osteoblasts

Timepoint

Four weeks after intervention, eight weeks after
intervention

Method of measurement

by microscopic observation

4

Description

Osteoclasts

Timepoint

Four weeks after intervention, eight weeks after
intervention

Method of measurement

by microscopic observation

5

Description

Foreign body reaction

Timepoint

Four weeks after intervention, eight weeks after
intervention

Method of measurement

by microscopic observation

Secondary outcomes

1

Description

Infection

Timepoint

Before intervention, during intervention, after
intervention

Method of measurement

Observation, examination

2

Description

The presence of the disease

Timepoint

Before intervention, during intervention

Method of measurement

By the veterinarian

Intervention groups

1

Description

Risedronate 2% gel; once, during surgery; localized in bone defect.

Category

Treatment - Drugs

2

Description

Placebo gel; once, during surgery; localized in bone defect.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University, Dental Tehran Branch

Full name of responsible person

Dr. Shirin Marzoughi

Street address

10th Neyestan St., Pasdaran Ave., Tehran, Iran.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Islamic Azad University, Dental Tehran Branch

Full name of responsible person

Dr. Arash Azizi

Street address

10th Neyestan St. , Pasdaran Ave. , Tehran, Iran.

City

Tehran

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 Islamic Azad University,

Dental Tehran Branch

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

Islamic Azad University, Dental Tehran Branch

Full name of responsible person

Dr. Shirin Marzoughi

Position

Dentist

Other areas of specialty/work

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Person responsible for updating data

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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