

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Determining concentration of Azitromycin in GCF after single dose administration in healthy subjects (by HPLC method)

Protocol summary

Summary

the goal of this study is determine Azithromycin concentration in Gingival Crevicular Fluid (GCF). With the use of a single dose of Azithromycin by a healthy individual deemed to be safe and may not cause health problems. In many case studies and treatment protocols, the use of a single dose by a healthy individual is common. Therefore, we select a group of 30 individuals who were healthy. The individuals consume a single dose of 250 mg; the GCF concentration of the drug is determine in 0, 6, 12 , 36 ,84 and 156 hour . For sampling we use paper cone #30 and gently place samples by applying the intrasulcular method to avoid any mechanical damages to interproximal areas of molar and canine. The samples placed in test tubs contain 0.5 ml NormalSalin and test tube tightly seal, and refrigerate at 4 degree Celsius to prevent deactivation with the enzyme. For determine concentration of Azithromycin with the use of the MTBE solution along with calcium chloride solution is performed . Ultimately, 20 micro liters of the extracted Azithromycin were injected to a device and the data Analyzed.

General information

Acronym

Concentration of Azithromycin in GCF

IRCT registration information

IRCT registration number: **IRCT201412033451N2**

Registration date: **2014-12-23, 1393/10/02**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-12-23, 1393/10/02

Registrant information

Name

Mahmood Khosravi samani

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2014-12-26, 1393/10/05

Expected recruitment end date

2015-02-24, 1393/12/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining concentration of Azitromycin in GCF after single dose administration in healthy subjects (by HPLC method)

Public title

Determining concentration of Azithromycin in GCF after single dose administration

Purpose

Treatment

Inclusion/Exclusion criteria

The eligible and healthy volunteers will be enrolled in this case study only after receiving adequate information regarding purpose of the subject research and providing their consent for participation. Inclusion criteria: are

having a gingival index less than 1.5 ; have adequate oral and general health conditions The exclusion criteria : are taking any oral medication in the last two weeks ; having an allergic reaction to Azithromycin ; gingivitis ; periodontitis ; showing any signs of gingival recession.

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Babol University of Medical Sciences

Street address

University of Medical Sciences-ganj afrooz avenu

City

babol

Postal code

41367

Approval date

2014-06-09, 1393/03/19

Ethics committee reference number

4232

Health conditions studied

1

Description of health condition studied

Determine Concentration of Azithromycin in gingival crevicular fluid

ICD-10 code

Z01.2

ICD-10 code description

Dental examination

2

Description of health condition studied

Concentration of Azithromycin in gingival crevicular fluid

ICD-10 code

Z01

ICD-10 code description

Other special examinations and investigations of persons without complaint or reported diagnosis

Primary outcomes

1

Description

Concentration of Azithromycin in GCF

Timepoint

Ine the 0 . 6 . 12 36 . 84 . 156 hours azithromycin concentrations in GCF checked.

Method of measurement

We used HPLC method for measuring Concentration of Azithromycin in GCF

Secondary outcomes

empty

Intervention groups

1

Description

A group of 30 individuals were selected and a single dose of 250 mg Azithromycin were prescribed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Periodontology , School of Dentistry , Babol University of Medical Sciences

Full name of responsible person

Dr Mahmood Khosravi Samani

Street address

Babol University of medical sciences , Ganj afrooz street

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dental Material Center , School of Dentistry , Babol University of Medical Sciences

Full name of responsible person

Dr Homaion Alaghemand

Street address

Babol University of Medical Sciences , Ganjafrooz street

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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

Dental Material Center , School of Dentistry , Babol 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

Babol University of Medical Sciences

Full name of responsible person

Dr Mahmood Khosravi Samani

Position

Periodontologist

Other areas of specialty/work

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Contact

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PhD in Pharmacology and Toxicology

Other areas of specialty/work

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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