Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of canine pre-inflammatory cytokines changes after applying the distaizing force to the opposite side of canine control teeth in patients who have extracted maxillary first premolars teeth and undergoing orthodontic treatment

Protocol summary

Summary

This study aimed to determine the level of TNF and IL6 pro-inflammatory cytokines in gingival crevicular fluid during orthodontic treatment.Ten patients presenting to the Orthodontic Department of School of dentistry, Qazvin University of Medical Sciences during 2016-2017 will be selected. Patients will be between 10-21 years and will be candidates for extraction of maxillary first premolars.The exclusion criteria are: current smoking or tobacco use and intake of immunosuppressants, non-steroidal anti-inflammatory drugs.A canine tooth will be randomly selected as the test group and will be subjected to distalization force while the contralateral canine tooth will be served as control. Using paper strip, gingival cervicular fluid will be collected at the mesial and distal of the test and control teeth prior to orthodontic force application (T0), one hour after orthodontic force application (T1) and 28 days after force application (T2). The level of TNF and IL6 will be measured in GCF using ELISA test.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017030632903N2**
Registration date: **2017-10-02, 1396/07/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-10-02, 1396/07/10

Registrant information

Name
Parviz Padisar Padisar
Name of organization / entity
Qazvin University of Medical Sciense
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Recruitment status

Recruitment complete

Funding source

Qazvin University of Medical Sciences

Expected recruitment start date

2017-03-19, 1395/12/29

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of canine pre-inflammatory cytokines changes after applying the distaizing force to the opposite side of canine control teeth in patients who have extracted maxillary first premolars teeth and undergoing orthodontic treatment

Public title

Assement of dental supporting tissue Inflammation during orthodontic treatment

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria are as follows: requiring extraction of maxillary first premolars and distalization of maxillary canine teeth by fixed orthodontic treatment; systemic health; no current smoking or tobacco use; no intake of antibiotics, immunosuppressants, drugs changing the hormonal balance such as contraceptives, antihistamines or non-steroidal anti-inflammatory drugs in the past four months (prior to study onset); no radiographic evidence of alveolar bone loss. The exclusion criteria are current smoking or tobacco use and intake of immunosuppressants, hormonal medications, antihistamines or non-steroidal anti-inflammatory drugs.

Age

From **10 years** old to **21 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

No

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Biomedical Research of Qazvin University of Medical Sciense

Street address

Qazvin University of Medical Sciense- shahid bahonar- Qazvin

City

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Postal code

3415815386

Approval date

2016-03-09, 1394/12/19

Ethics committee reference number

IR.QUMS.REC.1394.812

Health conditions studied

1

Description of health condition studied

proinflammatory cytokines

ICD-10 code

Z46.4

ICD-10 code description

Fitting and adjustment of orthodontic device

Primary outcomes

1

Description

Proinflammatory cytokines

Timepoint

before beginning of orthodontic treatment -after1 houer and 28 day following force application

Method of measurement

ELISA analyse

Secondary outcomes

1

Description

time

Timepoint

prior to orthodontic force application (T0), one hour after orthodontic force application (T1) and 28 days after force application (T2).

Method of measurement

houer and day

Intervention groups

1

Description

one week after extraction of maxillary first premolars and right before the bonding of orthodontic attachments, baseline GCF (T0) will be collected at the mesial and distal sites of control teeth using periopaper strip. After banding of first molars of the upper jaw and placement of trans palatal arch, 0.022 inch standard edgewise bracket will be bonded to the second premolar and canine teeth at control quadrants and after passively fixing the posterior teeth with stainless steel segment wire (0.019□0.025), For the control teeth, 0.017□0.025 titanium molybdenum alloy segment wire will be used to fabricate a simple vertical loop with 7mm height and 1mm width. Distal to the loop, a helix will be used then will be placed in the axillary tube of first molar and will be passively tied to the control canine tooth. Then, at different time intervals: one hour after wire placement (T1) and 28 days after wire placement (T2), the GCF again will be collected from both sides of the control tooth. The total volume of both cytokines will be determined in picograms (pg) According to Kate ELISA's

command.

Category

Other

2

Description

one week after extraction of maxillary first premolars and right before the bonding of orthodontic attachments, baseline GCF (T0) will be collected at the mesial and distal sites of test teeth using periopaper strip. After banding of first molars of the upper jaw and placement of trans palatal arch, 0.022 inch standard edgewise bracket will be bonded to the second premolar and canine teeth at test quadrants and after passively fixing the posterior teeth with stainless steel segment wire (0.019□0.025), For the test teeth, 0.017□0.025 titanium molybdenum alloy segment wire will be used to fabricate a simple vertical loop with 7mm height and 1mm width. Distal to the loop, a helix will be used to attach the coil spring and 20□ gable bend at each side of the loop will be used. Moreover, 30□ anti-rotation will be used at the mesial of the loop then will be placed in the axillary tube of first molar and will be tied to the test canine tooth Next, 150g distalizing force will be only applied to the test tooth using medium NiTi closed coil spring . It will be placed between the molar hook and loop. Then, at different time intervals: one hour after orthodontic force application (T1) and 28 days after force application (T2), the GCF again will be collected from both sides of the test tooth. The total volume of both cytokines will be determined in picograms (pg) According to Kate ELISA's command.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthodontic Department of Qazvin Dental School University of Medical Science

Full name of responsible person

Roya Hashemi Habybabadi

Street address

Department of Orthodontic, Dental School, Qazvin University of Medical Sciense, Bahonar Blv, Qazvin, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciense

Full name of responsible person

Maryam Tofangchiha

Street address

Dental School, Qazvin University of Medical Sciense, Bolvar Shahid Bahonar, Qazvin

City

Qazvin

Grant name

0

Grant code / Reference number

0

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

Yes

Title of funding source

Qazvin University of Medical Sciense

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

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Full name of responsible person

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City

Qazvin

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Qazvin University of Medical Sciense

Proportion provided by this source

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

Zahedan Dental School University

Full name of responsible person

Roya Hashemi Habibabadi

Position
MSD

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