Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Evaluation of pain and inflammatory factors in the gingival lining fluid in orthodontic treatment with NITI and CUNITI wires

Protocol summary

Study aim

determine the level of pain and inflammatory factors associated with Th17 (IL6, IL17a, IL17f, IL21) in gingival sulcus fluid in orthodontic treatment with niti and cuniti wires

Design

In this research, 24 eligible patients referring to Dentistry School of Shiraz University of Medical Sciences will be chosen purposefully and a code will be allocated to each one of them. Then, patients will randomly be divided in two groups of 12 people.

Settings and conduct

Due to extensive advertising that claim pain reduction in patients requiring fixed orthodontic treatment using copper alloy wires, a clinical trial study that compares these wires to other wires used in the treatment process, is necessary.This study will be supported by the Department of Organizational Research and the Ethics Committee of the Shiraz University of Medical Sciences in collaboration with the school of Dentistry and will be performed as a prospective double blind clinical trial in 2017 at the dentistry clinic of Shiraz University of Medical Sciences on patients requiring orthodontic treatment. Fixed orthodontist treatment with MBT system (0.022 * 0.028 slot) will be performed for all patients.The orthodontic wires used in this study are nickel-titanium (0.016 AO, USA) and orthodontic wires consisting of copper, nickel and titanium (0.016 Ormco, USA).). In this study, 24 patients that need orthodontic treatment (From persons referring to dental school of Shiraz University of Medical Sciences) will take orthodontic treatment by an orthodontist.Sample size is calculated by reviewing literatures and studies in the past also, determine the mean of applying orthodontic wires.Patients will be selected by easy sampling method, then using a random block method (Each block consists of 4 samples) will be divided into two groups.The demographic information questionnaire, such as date, age, sex, occupation, and entry and exit criteria for patients will be recorded.visual analogue scale(vas) and numeric pain rating scale(nrs) will be used to determine the pain level. This study will be double-blind.The researcher who performs laboratory tests and also the patient do not know about the type of wire.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Good general and periodontal health؛Orthodontic treatment plan must not include tooth extraction؛Age 12-25؛Crowding in the anterior mandibular segment Exclusion criteria:Chronic NSAID intake؛Presence of block outed tooth that does not allow the bracket to be placed in the initial bonding session؛Pregnancy؛Antibiotic therapy in the past 6 months؛Any previous orthodontic treatment؛Radiographic evidence of periodontal bone loss

Intervention groups

First intervention group: Twelve patients will be nited for 4 weeks using orthodontic wires. Second intervention group: 12 patients will use Cuniti wires for 4 weeks.

Main outcome variables

First out: The degree of pain in patients will be evaluated in each of the groups. Secondary outcome: To investigate the inflammatory factors associated with TH17, the gingival fluid is collected around the inoculum teeth.

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20111130008257N2**
Registration date: **2018-01-03, 1396/10/13**
Registration timing: **retrospective**

Last update: **2018-01-03, 1396/10/13**
Update count: **0**

Registration date

2018-01-03, 1396/10/13

Registrant information

Name

Maryam Karandish

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3628 9913

Email address

karandishm@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz university of medical sciences

Expected recruitment start date

2017-12-21, 1396/09/30

Expected recruitment end date

2018-01-04, 1396/10/14

Actual recruitment start date

2017-06-25, 1396/04/04

Actual recruitment end date

2017-08-31, 1396/06/09

Trial completion date

empty

Scientific title

Evaluation of pain and inflammatory factors in the gingival lining fluid in orthodontic treatment with NITI and CUNITI wires

Public title

Evaluation of pain in orthodontic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Good general and periodontal health Good oral hygiene Orthodontic treatment plan must not include tooth extraction Age: 12-25 years old Crowding in the anterior mandibular segment.

Exclusion criteria:

Chronic NSAID intake Presence of block outed tooth that does not allow the bracket to be placed in the initial bonding session Pregnancy Use of anti-inflammatory drugs in the month before the study Antibiotic therapy in the past 6 months Any previous orthodontic treatment Radiographic evidence of periodontal bone loss Spacing between the teeth in anterior segment of mandible

Age

From **12 years** old to **25 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **4**

Each participant will be sampled in 4 intervals. Samples will be taken before placing the wire, one hour after placing the wire, 24 hours after placing the wire and 48 hours after placing the wire.

Actual sample size reached: **24**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient has not been told which type of orthodontic wire is used. The researcher who evaluate the inflammatory factors does not know the type of wire used.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Shiraz University of Medical Sciences

Street address

Dentistry School, Shiraz University of Medical Sciences, Mehr Ave, Qasrodasht Blvd

City

Shiraz

Province

Fars

Postal code

1372-06-13

Approval date

2017-10-18, 1396/07/26

Ethics committee reference number

IR.SUMS.REC.1396.120

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Interleukin 21
ICD-10 code
ICD-10 code description

3

Description of health condition studied
Interleukin 6
ICD-10 code
ICD-10 code description

4

Description of health condition studied
Interleukin 17F
ICD-10 code
ICD-10 code description

5

Description of health condition studied
Interleukin 17A
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
pain
Timepoint
Pain assessment will be done before wire insertion,1 hour,12 hours,24 hours,48 hours,7 days and 14 days after wire insertion.
Method of measurement
questionnaire

2

Description
Interleukin 21
Timepoint
Interleukin 21 will be measured before wire insertion,1 hour,24 hours and 48 hours after wire insertion.
Method of measurement
BEAD BASED KITS

3

Description
Interleukin 6
Timepoint
Interleukin 6 will be measured before wire insertion,1 hour,24 hours and 48 hours after wire insertion.
Method of measurement
BEAD BASED KITS

4

Description
Interleukin 17F
Timepoint
Interleukin 17F will be measured before wire insertion,1 hour,24 hours and 48 hours after wire insertion.
Method of measurement
BEAD BASED KITS

5

Description
Interleukin 17A
Timepoint
Interleukin 17A will be measured before wire insertion,1 hour,24 hours and 48 hours after wire insertion.
Method of measurement
BEAD BASED KITS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: CuNiTi orthodontic wire, produced by Ormco, single application during study
Category
Treatment - Devices

2

Description
Intervention group: NiTi orthodontic wire, produced by American orthodontics, single application during study
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dental school of Shiraz University of Medical Sciences
Full name of responsible person
Mohsen Bagheri
Street address
Dentistry School of Shiraz University of Medical Science, Mehr Ave, Ghasrodasht Blvd
City
Shiraz
Province
Fars
Postal code
7371441589
Phone
+98 71 4331 4851
Fax
Email
mohsenbri@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Basir Hashemi
Street address
Dentistry school of Shiraz University of Medical Science, Mehr Ave, Qasrodasht Blvd
City
Shiraz
Province
Fars
Postal code
14336 - 71348
Phone
+98 71 4331 4851
Email
mohsenbri@yahoo.com
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
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohsen Bagheri
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
Shahid safaee Ave, Amir kabir Blvd
City
Shiraz
Province
Fars
Postal code
71767731327
Phone
+98 71 3839 0327
Fax
Email
mohsenbri@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohsen Bagheri
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
Shahid Safaee Ave, Amir Kabir Blvd
City
shiraz
Province
Fars
Postal code
7176773137
Phone
+98 71 3839 0327
Fax
Email
mohsenbri@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohsen Bagheri
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
Shahid safaee Ave, Amir Kabir Blvd
City
Shiraz
Province
Fars
Postal code
7176773137
Phone
+98 71 3839 0327
Fax
Email
mohsenbri@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available