

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A Comparison of color changes Between Four Different ligature brands: Ortho Technology and Ortho Organizers and American Orthodontics and Orthodontic Manufacturer - in Vivo Study

Protocol summary

Study aim

Evaluating the color changes for four different brands of elastic ligatures within patient's mouths: Ortho Technology, Ortho Organizers, American Orthodontics, and Manufacturing Orthodontics. Informing and providing feedback for patients of the color-changing patterns of ligatures with interest in athletics and clear ligatures.

Design

A clinical trial with parallel and Triple-blind groups was performed on 54 patients

Settings and conduct

we performed the sampling in three orthodontist offices located in the Kianpars region in the city of Ahwaz. patients and orthodontist specialists were not aware of which brands they were receiving. Every brand was placed in a jaw quarter on tooth numbers 1 to 3, such that all four brands were inside the patients' mouths simultaneously. On the day of placement and also four weeks after the placement, we measure the color changes by consulting with patients, orthodontists, as well as photography and Photoshop software.

Participants/Inclusion and exclusion criteria

Patients are accepted with no pre-existing birth-related defects with at least six teeth in upper and lower jaw.

Intervention groups

The use of ligatures in fixed orthodontic treatment and without any change in the time and process of treatment of patients, only 4 brands were used to evaluate the degree of change in the elastic color of the ligatures. First intervention : elastic ligatures from Ortho Technology (U.S.A) Were placed in patient's mouths for the duration of four weeks Second : elastic ligatures from Ortho Organizers (U.S.A) Were placed in patient's mouths for the duration of four weeks Third: elastic ligatures from Manufacturer Orthodontic (Italy) Were placed in patient's mouths for the duration of four weeks Fourth: elastic ligatures from American Orthodontics (Germany)

Were placed in patient's mouths for the duration of four

Main outcome variables

Color changes

General information

Reason for update

Instead of the code of ethics, the research project number was incorrectly entered, which was corrected in this update.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200815048409N1**

Registration date: **2020-10-03, 1399/07/12**

Registration timing: **retrospective**

Last update: **2020-10-08, 1399/07/17**

Update count: **1**

Registration date

2020-10-03, 1399/07/12

Registrant information

Name

sara gholamian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3623 9809

Email address

sara.gholamian100@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-24, 1399/06/03

Expected recruitment end date

2020-10-01, 1399/07/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A Comparison of color changes Between Four Different ligature brands: Ortho Technology and Ortho Organizers and American Orthodontics and Orthodontic Manufacturer - in Vivo Study

Public title
A Comparison of Color Changes in Elastic Ligatures - in Vivo Study

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
The Existence of at least 6 teeth in upper and lower jaw.
Exclusion criteria:

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **54**
More than 1 sample in each individual
Number of samples in each individual: **12**
Insertion of three different ligature brands in each jaw quarter.

Randomization (investigator's opinion)
Randomized

Randomization description
We assigned a number to each brand of ligatures Ortho technology:1 Ortho Organizers:2 Orthodontic Manofactory:3 and American Orthodontics:4. Then We randomly selected a number between 1 to 4 and placed a brand in each quarter of the patients jaw based on the random number.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The selection of brand for each ligature for each patient, orthodontist, and data analyst is blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahwaz JundiShapur University of Medical Sciences

Street address

School of Dentistry, JundiShapur University of Medical Sciences ,Ahwaz, Khuzestan, Iran

City

Ahwaz

Province

Khuzestan

Postal code

6135715794

Approval date

2020-01-22, 1398/11/02

Ethics committee reference number

IR.AJUMS.REC.1398.694

Health conditions studied

1

Description of health condition studied

Evaluation of color changes for four different ligature brands: Ortho Technology and Ortho Organizers and American Orthodontics and Manufacturer orthodontic

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Measuring the color changes of ligature in range of 1-4 with photography and softwares such as PhotoShop and CIE-LAB

Timepoint

At the beginning of the study and after 4 weeks.

Method of measurement

Questionnaire and photography

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: elastic ligatures from Ortho Technology (U.S.A) Were placed in patient's mouths for the duration of four weeks(28 days).

Category

Other

2**Description**

Intervention group Second : elastic ligatures from Ortho Organizers (U.S.A) Were placed in patient's mouths for the duration of four weeks(28 days).

Category

N/A

3**Description**

Intervention group Third: elastic ligatures from Manufacturer Orthodontic (Italy) Were placed in patient's mouths for the duration of four weeks(28days).

Category

N/A

4**Description**

Intervention group Fourth: elastic ligatures from American Orthodontics (Germany) Were placed in patient's mouths for the duration of four weeks(28 days).

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

3 Dental offices in Ahwaz

Full name of responsible person

Dr. Marzieh Mazhari

Street address

St 5, 12, 15,w. Kianpars, Ahwaz

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Ahmadzadeh

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Marzie.mazhari@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Sara Gholamian

Position

Dentistry Student

Latest degree

Bachelor

Other areas of specialty/work

Dentistry

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Unit 1, Classic building, Day and Esfahan st. intersection, Golestan, Ahwaz

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Sara Gholamian

Position

Dentistry student

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data can be shared in a way to keep the privacy of participants.

When the data will become available and for how long

Access can be started y the end of Year 1399

To whom data/document is available

Data can be accessible for professionals active in academia, industry, and orthodontic patients.

Under which criteria data/document could be used

We do not foresee any limitation for accessing this research's data.

From where data/document is obtainable

Please contact me through my email:
sara.gholamian100@gmail.com or my cell:
+989166007221

What processes are involved for a request to access data/document

Requests for accessing data can be made directly through my email.

Comments