

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Evaluation of hyaluronic acid injection's effect on reconstruction of 20 reduced interdental papilla in patients who apply Shiraz dental school

Protocol summary

Study aim

Evaluating the effect of hyaluronic acid injection on reconstruction of interdental papilla which has been lost

Design

20 interdental papilla which has deficiency in 5 patients

Settings and conduct

Patients referring to Periodontics department of Shiraz Dental School, who has interdental papilla deficiency, will be included in this study. Hyaluronic acid will be injected at interdental papilla and the area of interdental space will be measured before and 3, 6 months after injection.

Participants/Inclusion and exclusion criteria

Patients with plaque index below 20%; no caries; no smoking; no systemic disease; no deep pockets and healthy periodontium

Intervention groups

Hyaluronic acid injection in interdental papilla which has been lost

Main outcome variables

Increasing interdental papilla's volume and its area in photography

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200419047132N1**

Registration date: **2020-06-04, 1399/03/15**

Registration timing: **retrospective**

Last update: **2020-06-04, 1399/03/15**

Update count: **0**

Registration date

2020-06-04, 1399/03/15

Registrant information

Name

Ali Azadikhah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3631 9957

Email address

a2.azadikhah@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

2019-11-27, 1398/09/06

Actual recruitment end date

2019-12-21, 1398/09/30

Trial completion date

2020-06-06, 1399/03/17

Scientific title

Evaluation of hyaluronic acid injection's effect on reconstruction of 20 reduced interdental papilla in patients who apply Shiraz dental school

Public title

Evaluation of hyaluronic acid injection's effect on reconstruction of reduced interdental papilla

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have papilla recession in anterior of maxilla
Plaque index below 20%

Exclusion criteria:

Gingivitis or periodontitis at the region Smoking Taking
drugs which cause gingival enlargement Systemic
disease which effects periodontal status

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **5**
More than 1 sample in each individual
Number of samples in each individual: **4**
reduced interdental papilla
Actual sample size reached: **5**
More than 1 sample in each individual
Actual sample size in each individual: **4**
Reduced interdental papilla loss

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
Use of Acid hyaluronic gel with higher viscosity, injection in 2 points of papilla

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Dentistry faculty, Ghomabad, Ghasraldasht Ave.

City

Shiraz

Province

Fars

Postal code

7185981633

Approval date

2020-04-08, 1399/01/20

Ethics committee reference number

IR.SUMS.DENTAL.REC.1399.030

Health conditions studied

1

Description of health condition studied

Interdental papilla loss

ICD-10 code

K08.9

ICD-10 code description

Disorder of teeth and supporting structures, unspecified

Primary outcomes

1

Description

Amount of interdental papilla reconstruction

Timepoint

3 months and 6 months after intervention

Method of measurement

Measuring the area with Imagej software

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Injection of 0,2ml Acid hyaluronic gel in the interdental papilla wich has been lost, 3 times with 2 weeks interval

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Dentistry faculty

Full name of responsible person

Ali Azadikhah

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NO 57, Pasdaran Ave, Moalem Squere

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7185981633

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Azadeh Andishe Tadbir

Street address

Dentistry faculty-Ghomabad-Ghasrodaht-shiraz

City

Shiraz

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Postal code

71956-15878

Phone

+98 71 3627 0322

Email

Denth_pazho@sums.ac.ir

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

Ali Azadikhah

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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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	patients sex and age and region of involvement
Statistical Analysis Plan	When the data will become available and for how long
Yes - There is a plan to make this available	six month after publishing the results
Informed Consent Form	To whom data/document is available
Yes - There is a plan to make this available	the ones who demand
Clinical Study Report	Under which criteria data/document could be used
Yes - There is a plan to make this available	Nothing spacial
Analytic Code	From where data/document is obtainable
Yes - There is a plan to make this available	Ali Azadikhah a2.azadikhah@gmail.com
Data Dictionary	What processes are involved for a request to access data/document
Undecided - It is not yet known if there will be a plan to make this available	reason of demand via email
Title and more details about the data/document	Comments