Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 hyaloronic acid injection on recounstruction 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. Hyaloronic 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 whith plaque index below 20%; no caries; no smoking; no systemic disease; no deep pockets and healthy perodontium
Intervention groups
Hyaloronic acid injection in interdental papilla which has been lost
Main outcome variables
Increasing interdental papilla's volume and it's 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)
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+98 71 3631 9957
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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 bellow 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 hyaloronic 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 monthes 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 hyaloronic 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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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
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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

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Person responsible for updating data

Contact

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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

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

Title and more details about the data/document

patients sex and age and region of involvement

When the data will become available and for how long

six month after publishing the results

To whom data/document is available

the ones who demand

Under which criteria data/document could be used

Nothing spacial

From where data/document is obtainable

Ali Azadikhah a2.azadikhah@gmail.com

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

reason of demand via email

Comments