Comparing two different dental bridge designs made of translucent zirconia

Submission date 02/05/2020	Recruitment status No longer recruiting	Prospectively registeredProtocol
Registration date 05/05/2020	Overall study status Completed	Statistical analysis planResults
Last Edited 05/05/2020	Condition category Oral Health	Individual participant dataRecord updated in last year
Plain English summary of protocol		

Background and study aims

Translucent zirconia is a new dental material with high potential for dental prosthesis (false teeth); the research is comparing two different dental bridges designs made of translucent zirconia, in the matter of survival rate and clinical performance.

This research is important to develop a protocol for the treatment of missing teeth in specific conditions.

Who can participate?

Adults over 18 years who have lost the second premolar in one side or more.

What does the study involve?

Participants will be randomly allocated to receive either anatomic designed translucent zirconia bridges or traditional designed translucent zirconia bridges.

What are the possible benefits and risks of participating?

There will be no harms for the patients, and the new material has passed through multiple laboratory test before clinical trials.

Where is the study run from?

Damascus University - faculty of dental medicine (Syria)

When is the study starting and how long is it expected to run for? March 2018 to October 2020

Who is funding the study? Investigator initiated and funded

Who is the main contact? Dr Shukri Alsamara, Shekrysamara89@gmail.com

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

217/T.M

Study information

Scientific Title

The effect of the prosthesis design (monolithic, traditional) made of translucent zirconia on clinical performance: randomized controlled trial

Study objectives

There is significant difference in clinical performance between anatomic and traditional design.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 24/01/2017, Ethical Committee of the Faculty of Dental Medicine (Damascus University, Damascus, Syria; +963 113341864; manager@hcsr.gov.sy), ref: 270/T.M

Study design

Interventional randomized control trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Patients who have lost one tooth or more and in need for dental prosthesis.

Interventions

Patients have been divided randomly into two group:

Group A: received anatomic designed translucent zirconia bridges.

Group B: received traditional designed translucent zirconia bridges.

Follow up for two years.

Intervention Type

Other

Primary outcome measure

Measured using visual inspection at one month, 6 months, one year, two years:

- 1. Prothesis fracture: no fracture/color change or small fracture/zirconia fracture/complete fracture in the prosthesis
- 2. Marginal fit: complete fit/there is evidence of leakage/the probe can access the prothesis /prothesis is movable
- 3. Discoloration: no discoloration/surface discoloration/discoloration towards the pulb

Secondary outcome measures

Oral health index collected using oral examination and with UNC15 probe (university of North Carolina). Oral data collected from each patient on three different time intervals (after one month, after 6 months, after one year, after two years)

- 1. Plaque index (PI)
- 2. Gingival index (GI)
- 3. Decayed, missing, filled teeth index

Overall study start date

24/01/2017

Completion date

01/10/2020

Eligibility

Key inclusion criteria

- 1. Lost second premolar in one side or more
- 2. Good oral hygiene
- 3. The pontics have good stability
- 4. Absence of oral dysfunction

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

30

Key exclusion criteria

The clinical crown length of the pontics is less than 3 mm

Date of first enrolment

01/03/2018

Date of final enrolment

01/10/2019

Locations

Countries of recruitment

Syria

Study participating centre

Damascus university

Faculty of dental medicine Almazzah **Damascus** Syria

Sponsor information

Organisation

Damascus University

Sponsor details

Almazzah Damascus Syria

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Sponsor type

University/education

Website

http://damasuniv.edu.sy/

ROR

https://ror.org/03m098d13

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

01/11/2020

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date