A randomized controlled clinical trial of Titanium and Zirconia implants in maxillary single tooth replacement

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To compare, in a randomized controlled clinical trial, titanium and zirconia implants for the replacement of a single upper premolar after 1 and 3 years of function.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Dental and gingival conditions
Study type	Interventional

Summary

ID

NL-OMON47613

Source
ToetsingOnline

Brief title
Titanium and Zirconia implants in maxillary single tooth replacement

Condition

- Dental and gingival conditions

Synonym
Tooth loss

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Grant van Internationaal Team voor Implantology (ITI)

Intervention

Keyword: Implant, RCT, Titanium, Zirconium

Outcome measures

Primary outcome

Marginal bone loss as measured on a radiograph after 1 and 3 years compared to

baseline.

Secondary outcome

- plaque accumulation

- calculus

- pocket probing depth

- bleeding on probing

- contentment

Study description

Background summary

For the replacement of a missing tooth with an implant, titanium is currently the biomaterial of choice. Good results have been reported in the literature, but titanium has some drawbacks as well. The main concern is that it is grey, which can cause blue-greyish shimmering, which may cause esthetic problems. Besides, some patients prefer a metal-free sollution. Zirconia may be a good alternative. Recently a new zirconia implant was launched (Pure Straumann, Zwitserland), of which expectations are high, but not backed up by evidence that is, may serve as well as titanium.

Study objective

To compare, in a randomized controlled clinical trial, titanium and zirconia implants for the replacement of a single upper premolar after 1 and 3 years of function.

Study design

A randomized clinical trial

Intervention

Placement of a titanium or zirconia implant and the provision of a crown.

Study burden and risks

No risks other than those commonly associated with the placement of an implant (minor pain and swelling and the chance on implant loss), not different among both research groups.

For subjects a limited extra investment in time is expected (1 additonal hour). It is regular care, both the treatment itself and the documentation of the outcome measures.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Missing first or second premolar in the maxilla
Wish to replace the missing premolar with an implant
Bone height >=10 mm beneath the maxillary sinus

Exclusion criteria

Missing teeth mesial or distal from implantation site
Orthodontic treatment at the time of impression taking
Severe bruxism
Acute periodontitis
History of implant loss
Documented extreme gagging reflex
Poor medical condition (ASA* score 3 or higher)35
Previous therapeutic radiation of the head -neck region
Chronic pain in orofacial system
Younger than 18 years at time of inclusion

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-04-2017
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	tooth implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-02-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-05-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL58957.042.16