# Zirconia in permucosal applications: aesthetic, biological and microbiological aspects; a pilot study.

Published: 09-01-2007
Last updated: 10-08-2024

This study aims to investigate the reaction of the peri-implant tissues to these materials when used in oral implant dentistry.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON30150

**Source**
ToetsingOnline

**Brief title**
Zirconia in permucosal applications; a pilot study

### Condition

- Other condition
- Dental and gingival conditions

**Synonym**
The response of mucosa to zirconium

**Health condition**

Esthetisch en functioneel herstel in de (gedeeltelijk) tandeloze kaak

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht
**Source(s) of monetary or material Support:** Ministerie van OC&W,Astra Zeneca

## Intervention

**Keyword:** dental implant, peri-implant mucosa, Zirconia

## Outcome measures

### Primary outcome

The primary endpoint of the study is our preference for titanium or zirconium

based on the number of inflammatory cells in the soft tissues adjacent to both

materials.

### Secondary outcome

Furthermore, the peri-implant mucosa around both abutments is investigated

visually, biologically and microbiologically.

# Study description

### Background summary

Little is know about the reaction of the permucosal tissues to zirconium and titanium.

### Study objective

This study aims to investigate the reaction of the peri-implant tissues to these materials when used in oral implant dentistry.

### Study design

Twenty edentulous subjects receive 2 implants in the interforaminal region of the mandible. In a spit mouth study design, one implant is provided with a zirconium and the other with a titanium aburment.

### Intervention

not applicable

**Study burden and risks**

We feel that there is no extra burden or risk concerned when compared to our common and standard treatment protocol in these patients.

# 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

Fully edentulous patients with functional lower denture problems and a minimal height of the mandible in the midline of 13 mm. Patents' health allows a oral surgical intervention under local anesthesia.

### Exclusion criteria

ASA score 3 or more or when implant-supported overdenture (bar-clip with distal extensions) treatment is indicated.

## Study design

### Design

| | |
|---|---|
| Study phase: | 4 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 30-11-2007 |
| Enrollment: | 20 |
| Type: | Actual |

## Ethics review

Approved WMO

| | |
|---|---|
| Date: | 09-01-2007 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |

## 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 | NL11687.041.06 |