A longitudinal randomized clinical trial of participants satisfaction of two mandibular implant-retained overdentures, with ball, bar or locator attachment, in patients with severe resorption of the mandible.

Published: 13-10-2011
Last updated: 29-04-2024

Primary Objective:Is there a difference in patient satisfaction of the treatment in patients with a edentulous mandibular atrophic ridge comparing treatment with 2 dental implants and one of the three attachment types: ball-attachments, bar-...

Ethical review	Approved WMO
Status	Pending
Health condition type	Lifestyle issues
Study type	Interventional

Summary

ID

NL-OMON35749

Source
ToetsingOnline

Brief title
Dental implants and suprastructure trial 2 (the suprastructure trial)

Condition

- Lifestyle issues
- Bone and joint therapeutic procedures

Synonym
dental implants, mandibular implant-retained overdenture, prosthesis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: clinical trial, longitudinal, mandibular implant-retained, randomized

Outcome measures

Primary outcome

During several adjusted moments NRS scores will be rececorded for:

1. function of the prosthesis

2. Patient satisfaction (concerning the prosthesis)

3. Pain and discomfort

Secondary outcome

The following parameters will be registered:

1. The number of unplannded patient contacts.

2. The total costs op the prosthetic tratment (as declared by dentist and

dental laboratory).

3. Postoperative painmedication (diary).

Study description

Background summary

For approximately 20 years dental implants are more and more used for retention of mandibular overdentures. Meanwhile the effectiveness and the reliability of this treatment have been proven sufficiently in elaborate scientific research(Wismeijer et al., 1997 a,b 1999).
For the treatment of the edentate lower jaw 2,3 or 4 dental implants are chosen and there are several posible suprastructures to go with them. The different kind of suprastructures, on which the dental prosthesis can be attached, are the ball-attachments, bar-attachments or the locators.
In this study we try to answer the question whether there is a difference in patient satisfaction of the treatment, comparing patients with 2 dental implants with an overdenture on one of those three attachment types: ball-attachments, bar-attachments or the locators.

Study objective

Primary Objective:
Is there a difference in patient satisfaction of the treatment in patients with a edentulous mandibular atrophic ridge comparing treatment with 2 dental implants and one of the three attachment types: ball-attachments, bar-attachments or the locators?

Null Hypothesis:
Patient satisfaction of treatment with an overdenture on 2 dental implants with one of the three attachment types: ball-attachments, bar-attachments or the locators, is comparable.

Secondary Objectives:
1. Is there a difference in total costs between the 3 treatment options?
2. Is there a difference in number of patient contacts between the 3 treatment options?
3. Is there a difference in perception and postoperative complications between the 3 treatment options?
4. Is there a difference in number of unplannded patient contacts between the 3 treatment options?

Study design

Longitudinal, Randomized, Clinical Trial.

Intervention

n/a

Study burden and risks

The study varies only in minor details from the standard procedure.

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

1. Edentulous upper and lower jaw.
2. The need of 2 dental implants in the lower jaw urged by dental surgeon and dentist during a combined consultation.

Exclusion criteria

1. Simultaneous extractions or vestibuloplasty.
2. Bone-augmentation.
3. Simultaneous placement of dental implants in the maxilla.
4. Immune compromised patients.
5. Patients that underwent radiotherapy in the head and neck area.

6. Infections in the vicinity of the planned implant sites.
7. Pregnancy or lactating.
8. Less than 3 months after the last tooth-extraction.
9. Treated or under treatment with oral or intravenous amino-bisphosphonates.
10. Earlier placed dental implants.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2011
Enrollment:	660
Type:	Anticipated

Ethics review

Approved WMO

Date:	13-10-2011
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL36514.075.11