

Single tooth replacement with dental implants in the aesthetic zone. A randomized clinical trial of different implant designs and different times of restoration.

Submission date 27/01/2006	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 27/01/2006	Overall study status Completed	☐ Protocol
Last Edited 19/08/2009	Condition category Oral Health	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

NTR422

Study information

Scientific Title

Study objectives

The purpose of this study is to evaluate and compare the aesthetic definitive outcome of:

1. Three different implant designs
2. Two different times of restoration, namely immediate and conventional restoration

The null hypothesis is that there are no differences in the definitive aesthetic outcome of different implant designs or times of restoration.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Primary study design

Interventional

Study design

Randomised open label active controlled parallel group

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Dental implant, single-tooth

Interventions

Patients are randomly assigned to the following study groups:

Group I: a dental implant of the NobelReplace Tapered system is inserted in the anterior zone of the maxilla. After an osseointegration period of three months a temporary restoration is made.

Group IIA: a dental implant of the NobelReplace Groovy system is inserted in the anterior zone of the maxilla. Within 24 hours a temporary restoration is placed.

Group IIB: a dental implant of the NobelReplace Groovy' system is inserted in the anterior zone of the maxilla and a temporary restoration is made after three months

Group III: a dental implant of the NobelPerfect system is inserted in the anterior zone of the maxilla and a temporary restoration is made after three months

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Aesthetic Index according to Meijer et al. 2005

Key secondary outcome(s)

1. Implant survival
2. Marginal bone resorption
3. Papil-index

- 4. Recession
- 5. Patient satisfaction

Completion date

01/09/2008

Eligibility

Key inclusion criteria

1. The patient is 18 years or older
2. The missing or lost tooth is an incisor (central or lateral), a canine or a first bicuspid in the maxilla. The adjacent teeth are natural teeth.
3. Sufficient healthy and vital bone to insert a dental implant with a minimum length of 10 mm and at least 3.5 mm in diameter. In case of insufficient bone volume, a bone augmentation procedure will be performed with autologue bone. After three months of healing, the dental implant will then be inserted.
4. The implant site must be free from infection
5. Adequate oral hygiene (modified plaque index and modified sulcus bleeding index <1)
6. Sufficient mesio-distal, bucco-lingual, and interocclusal space for placement of an anatomic restoration
7. If necessary, the temporary restoration can be designed free from occlusal contact
8. The patient is capable of understanding and giving informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Medical and general contraindications for the surgical procedures
2. Presence of an active and uncontrolled periodontal disease
3. Presence of pathologic microflora
4. Bruxism
5. Site of implant placement is an extraction wound younger than three months
6. Smoking (patients who stop smoking six weeks before the operation can be included)
7. A history of local radiotherapy to the head and neck region

Date of first enrolment

01/09/2004

Date of final enrolment

01/09/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Center Groningen

Groningen

Netherlands

9713 GZ

Sponsor information

Organisation

University Medical Centre Groningen (UMCG) (Netherlands)

ROR

<https://ror.org/03cv38k47>

Funder(s)

Funder type

Industry

Funder Name

Nobel Biocare (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration