

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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# 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

### Study design

Randomised open label active controlled parallel group

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

### 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 measure**

Aesthetic Index according to Meijer et al. 2005

**Secondary outcome measures**

1. Implant survival
2. Marginal bone resorption
3. Papil-index
4. Recession
5. Patient satisfaction

**Overall study start date**

01/09/2004

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

120

**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)

**Sponsor details**

Hanzeplein 1

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Netherlands

9713 GZ

**Sponsor type**

Not defined

**ROR**

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

# Funder(s)

## Funder type

Industry

## Funder Name

Nobel Biocare (Switzerland)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration