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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

Registration date
27/01/2006

Overall study status
Completed

Last Edited
19/08/2009

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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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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