ISRCTN57251089 https://doi.org/10.1186/ISRCTN57251089

Immediate placement of a single-tooth implant after extraction in the aesthetic zone

Submission date
23/12/2011

Recruitment status
No longer recruiting

Registration date
09/02/2012

Overall study status
Completed

Last Edited
30/06/2015

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Tooth extraction is necessary when all other dental treatments to preserve a tooth did not help. After tooth extraction the underlying bone structure and the surrounding soft tissues collapse if not preserved. In the visible area seen upon full smile (aesthetic zone) the preservation of these tissues are important. The aesthetic success of a dental restoration is determined by the harmony of the underlying bone structure and these surrounding soft tissues. It is not known to what extend immediate placement of a single implant can do to preserve these tissues if there is sufficient bone or if there is a bony defect after the tooth extraction.

Who can participate?
In this study 76 healthy human adults (> 18 year) with a failing tooth in the aesthetic zone of the upper jaw (maxilla) can participate.

What does the study involve?
The participants undergo the same treatment procedures, only within a different time schedule. For this study a NobelActive implant (Nobel Biocare AB, Gothenburg, Sweden) is used. Depending on the remaining bone after tooth extraction, the treatment strategy is as follows:
Sufficient bone: the implant is immediately placed after tooth extraction and immediately restored with a temporary crown. One stage surgery.
Sufficient bone: the implant is immediately placed after tooth extraction but restored after 3 months with a temporary crown. Two stage surgery.
Insufficient bone: the implant is immediately placed after tooth extraction but restored after 3 months with a temporary crown. Two stage surgery.
Insufficient bone: a guided bone augmentation takes place after tooth extraction. 3 months later the implant is placed in a healed site. 3 months later the implant is restored with a temporary crown. Three stage surgery. This is the conventional way.
All participants have three additional research appointments. The first appointment is prior to the surgery, second after definite crown is placed and third is one year after the placement of the definite crown.
During these appointments digital intra oral pictures are taken. Examination of the underlying bone structure is done by X-rays and the surrounding soft tissues are measured with a dental instrument. In the last two appointments also a questionnaire has to be filled out.

What are the possible benefits and risks of participating?
All participants get the same discount on their bill. Because they are participating, the costs of the dental implant are reduced. There are no additional costs for this study. The only risk of participating in this study can be implant failure. Implant failure can occur within every study group. When this occurs the treatment will be repeated.

Where is the study run from?
This study takes place in the University Medical Centre Groningen (UMCG)

When is the study starting and how long is it expected to run for?
The study started in October 2010 and will run until December 2012. All participants have been recruited.

Who is funding the study?
University Medical Centre Groningen (UMCG) is funding this study.

Who is the main contact?
Dr. K.W. Slagter
k.w.slagter@umcg.nl

Contact information

Type(s)
Scientific

Contact name
Prof Gerry Raghoebar

Contact details
Hanzeplein 1
Groningen
Netherlands
9700 RB
+31 (0)503 610 213
g.m.raghoebar@umcg.nl

Additional identifiers

Protocol serial number
NL32240.042.10

Study information

Scientific Title
Immediate placement and/or restoration of a single-tooth implant after extraction in the anterior maxilla: a randomized clinical trial

Study objectives

Investigate the influence on the hard and soft tissues of immediate placement of a single implant in an extraction socket in the anterior maxilla.

Null hypothesis: is that there are no differences in the hard and soft tissues and aesthetic outcome

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Local Medical Ethics Committee [Medische Etische Toetsingscommissie (METc)], 29/09/2010, ref: 2010/246
2. General Assessment and Registration [Algemeen Beoordelings en Registratieformulier (ABR)] ref: NL 31761.042.10

Primary study design
Interventional

Study design
Randomised open-label active-controlled parallel-group trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Failing tooth in the aesthetic zone

Interventions
2 groups with suffcient bone and 2 groups with insufficient bone. They are randomised depending on the bony defect. An envelope is opened after the bony defect is determined.

1. Sufficient bone: the implant is immediately placed after tooth extraction and immediately restored with a temporary crown. One stage surgery.
2. Sufficient bone: the implant is immediately placed after tooth extraction but restored after 3 months with a temporary crown. Two stage surgery.
3. Insufficient bone: the implant is immediately placed after tooth extraction but restored after 3 months with a temporary crown. Two stage surgery.
4. Insufficient bone: a guided bone augmentation takes place after tooth extraction. 3 months later the implant is placed in a healed site. 3 months later the implant is restored with a temporary crown. Three stage surgery. This is the conventional way.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Changes in peri-implant hard tissues (marginal bone levels, mesial and distal)

Key secondary outcome(s)
1. Implant survival
2. Peri-implant soft tissues (modified Plaque-index, modified Bleeding-Index, papil index, probing depth,recession, width of keratinized epithelium)

3. Patient satisfaction (OHIP-14)
4. Aesthetic Index (Meijer et al. 2005)

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. The patient is 18 years or older
2. The replacing tooth is an incisor (central or lateral), a canine or a first premolar in the maxilla. The adjacent teeth are natural teeth
3. The implant site must be free from infection
4. Adequate oral hygiene
5. Sufficient mesio-distal, bucco-lingual, and interocclusal space for placement of an anatomic restoration
6. 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
06/10/2010

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Netherlands

Study participating centre
Hanzeplein 1
Groningen
Netherlands
9700 RB

Sponsor information

Organisation
University Medical Centre Groningen (Netherlands)

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Centre Groningen (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2015		Yes	No