Post extraction immediate implant placement versus early implant placement assessing computer-guided surgery to achieve the correct implant position. A volumetric analysis of changes in the surrounding soft and hard tissue. A prospective randomized controlled trial.

Published: 23-05-2014
Last updated: 20-04-2024

The primary purpose of this study is to investigate whether immediate implant placement, in ideal position, might preserve soft and hard tissue shape and contours, avoiding the need for extended augmentation and as a result achieving better esthetic...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40819

Source
ToetsingOnline

Brief title
Immediate versus early implant placement after extraction

Condition

- Other condition

Synonym
Lost or hopeless uppertooth of the upper jaw

Health condition

hopeloze of verloren boventand (hoektand tot hoektand in de bovenkaak)

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Centrum Tandheelkunde Amsterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Straumann

Intervention

Keyword: bone level, Dental implants, immediate, implant position, post extraction

Outcome measures

Primary outcome

- Hard tissue changes

- Soft tissue changes

- Aesthetic assessment using the Pink and White Score (PES/WES)

Secondary outcome

- Precision of the computer-guided surgery

Study description

Background summary

Post extraction sockets in the esthetic area have been subject of discussion among clinicians for many years. Buccal bone changes, its consequences for soft tissue changes and finally it*s impact on the esthetic outcome has been described in the literature by different research groups. Yet immediate implant placement with correct implant positioning can play a positive role to achieve a high-end esthetic result and reduce or inhibit the resorption of the buccal

bone.

Study objective

The primary purpose of this study is to investigate whether immediate implant placement, in ideal position, might preserve soft and hard tissue shape and contours, avoiding the need for extended augmentation and as a result achieving better esthetic outcomes. Hypothesis of this study is to have significantly less alveolar ridge resorption (<1.5mm in vertical and <3mm in horizontal plain) when implants are inserted immediately after extraction in the correct position in relation to residual buccal bone conducting computer guided surgery, achieving acceptable esthetic results.

The secondary purpose of this study is to examine the precision of the computerized guided surgery to insert implants in the fresh extraction sockets to achieve correct 3D implant positioning.

Study design

This is a randomized, open interventional clinical trial in which 2 (widely accepted) treatments will be compared to eachother.

Intervention

Randomized assignment to treatment group

Study burden and risks

The patients do not have to come to ACTA for more or less control visits than usual. The risks are not different or greater than those of a treatment outside of the study.

Contacts

Public
Academisch Centrum Tandheelkunde Amsterdam

Gustav Mahlerlaan 3004
Amsterdam 1081 LA
NL
Scientific
Academisch Centrum Tandheelkunde Amsterdam

Gustav Mahlerlaan 3004

Amsterdam 1081 LA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* At least 18 years of age;
- Patients with at least one hopeless anterior upper tooth (canine to canine in the upper jaw) requiring extraction and implant of replacement
* Able to understand and sign the informed consent;
* Absence of visible active inflammation;
* No large bony defect or abnormality of the bone visible on the x-ray;
* Single gap after extraction, central or lateral incisor or cusped in the maxilla;
* Natural teeth on both sides of the lost tooth;
* Adequate oral hygiene.

Exclusion criteria

* ASA-score * III;
* Presence of active clinical periodontitis as expressed by probing depths * 4mm and bleeding on probing on the adjacent teeth;
* History of radiotherapy in the head and neck region;
* Use of intravenous bisphosphonate medication.
- Smoking more than 10 sigarettes per day

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2014
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Generic name:	Dental implant system and Guided surgery system
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	23-05-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL47952.029.14