Assessment of the Long-Term Survival of Dental Implants in Cleft Patients

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The primary goal is to assess the survival rate of dental implants placed in cleft patients compared to non-cleft patients. Secondary objectives will be: evaluation of the parameters on the survival of dental implants (smoking, oral hygiene, length...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON56834

Source
ToetsingOnline

Brief title
Dental Implant survival in cleft patients

Condition

- Other condition

Synonym
harelip, orofacial cleft

Health condition

Kaakchirurgische ingrepen, implantologie

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cleft lip, cleft palate, dental implant, survival analysis

Outcome measures

Primary outcome

From the patients who received a dental implant data will be retrospectively collected about when they received the implant, possible parameters which could impact the survival rate (smoking, oral hygiene, length of dental implant, diameter of dental implant, interval between secondary cleft repair and implant placement, interval between tertiary cleft repair and implant placement, type of tertiary cleft repair (horizontal, vertical or both)), and the date of failure if there was an indication of removal of dental implant or indication that the dental implant lost functionality.

Secondary outcome

From the patients who received a dental implant data will be prospectively collected. The patients will be visiting once. During this visit a calibrated periodontal probe will be used to measure BoP and PD, a radiograph of the implant will be taken using a standardized method and PROM will be measured using the Dutch translation of the Oral Health Impact Profile (OHIP- NL49) for the situation before and after implantation of an dental implant.

Study description

Background summary

Hypodontia is a common phenomenon in patients with orofacial clefts. The upper lateral incisor is the most susceptible to be missing in case of hypodontia. Nowadays, dental implants in patients with an alveolar cleft are seen as an excellent treatment option, because it is a safe procedure with a good prognosis and low morbidity. There is a lack of papers reporting the difference of survival rates of dental implants between cleft and non-cleft patients with a longer follow-up than 5 years. Also, not much is known about the satisfaction of patients who received a dental implant.

Study objective

The primary goal is to assess the survival rate of dental implants placed in cleft patients compared to non-cleft patients. Secondary objectives will be: evaluation of the parameters on the survival of dental implants (smoking, oral hygiene, length of dental implant, diameter of dental implant, interval between secondary cleft repair and implant placement, interval between tertiary cleft repair and implant placement, type of tertiary cleft repair (horizontal, vertical or both)), the difference in patient reported outcomes measurements (PROM) before and after implantation of an dental implant and evaluation of the periodontal parameters (pocket depth (PD), bleeding on probing (BoP) and a standardized intraoral radiograph).

Study design

Cohort study

Study burden and risks

This study is a non-interventional study comparing results from a standard procedure between two groups. The procedure has been used in standard of care and all used devices are CE-marked, therefore the patients are not in any risk other than the procedure they would be having anyway, and a structured risk analysis is not deemed necessary. The patients will be visiting once. During this visit a calibrated periodontal probe will be used to measure BoP and PD, a radiograph of the implant will be taken using a standardized method and PROM will be measured using the Dutch translation of the Oral Health Impact Profile (OHIP- NL49).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. At least 18 years old.
2. Has been treated for cleft condition.
3. Received a dental implant in replacement of one or more of the maxillary incisors or canine.

Exclusion criteria

1. Disability (mental and/or physical) to maintain basic oral hygiene procedures
2. Condition which affects the healing of bone.
3. Patients unwilling or incapable of understanding and signing the informed

consent for secondary measurements.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	17-06-2021
Enrollment:	69
Type:	Anticipated

Ethics review

Approved WMO

Date:	10-06-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL74784.078.20