ISRCTN97142521 https://doi.org/10.1186/ISRCTN97142521

Early Loading of Palatal Implants (ortho-type II) a prospective multicenter randomised controlled clinical trial

Submission date 20/02/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/03/2007	**Overall study status** Completed	
Last Edited 19/07/2021	**Condition category** Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Britta A. Jung

Contact details
Department of Orthodontics
University Hospital of Mainz
Augustusplatz 2
Mainz
Germany
55131
+49 6131 172692
brjung@uni-mainz.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Early Loading of Palatal Implants (ortho-type II) a prospective multicenter randomised controlled clinical trial

Acronym
ELPI

Study objectives
The objective of the clinical study proposal will be to investigate the performance of early functional palatal implant loading in order to find out whether early orthodontic loading without the typical healing period is a clinically safe procedure - and might, thus, be justified to accelerate active orthodontic treatment. Concerning this matter the following null hypothesis will be addressed: There will be no difference between standard therapy (implant loading after a post-surgical healing period of 12 weeks) and early loading group concerning implant failure rate.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the State Medical Council of Rhineland-Palatinate, approved on 16 Oct 2006. Ref: 837.210.06 (5308)

Study design
Prospective multi-center randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Orthodontic treatment

Interventions
Implant loading after a post-surgical healing period of 12 weeks vs early implant loading within 1 week post implantation.

Surgical enquiry:
Prof M. Kunkel
Department of Oral and Maxillofacial Surgery
University Hospital of Mainz
55131 Mainz
Germany
Email: kunkel@mkg.klinik.uni-mainz.de
Tel: +49 6131 175458

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Implants' stability after a loading time of 6 and 12 months of function after implant placement. The criteria of implant success are:
1. Implant survival
2. No abnormal mobility

Secondary outcome measures
Secondary clinical endpoints will include:
1. Achievement of partial orthodontic treatment success 12 months after implant insertion
2. Quantity of direct implant-bone interface of the removed bone specimens
3. Patients acceptance rate of palatal implants
4. Anchorage loss of the anchor tooth unit and overall success after completion of active treatment.

As a tertiary endpoint, a histological and microtomography evaluation of all retrieved implants (about 2-3 years after placement) will be performed to obtain data on the performance of the sandblasted and acid-etched surface (SLA) surface in human bone.
In addition, a comparison between histomorphometric and microtomographic analyses will be performed on each specimen to evaluate the possibility of microtomography and to calibrate the technology for implant osseointegration assessment. Moreover, the measurement reliability of the resonance frequency measuring device (OsstellTM mentor) in the assessment of implant stability will be evaluated by comparison between ISQ (implant stability quotient) values and the quantity of direct implant-bone interface of all retrieved implants.

Overall study start date
01/12/2006

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Need and desire for an implant-supported orthodontic treatment, needed for maximum anchorage

2. Patients must have adequate bone quantity based on lateral radiographs
3. Patients must have adequate oral hygiene and normal wound healing capacity
4. Patients must be willing to be present for clinical examinations and must have signed the informed consent form
5. Female patients may only participate if they have undergone a urine pregnancy test for pregnancy exclusion

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
124

Key exclusion criteria
Systematic exclusion criteria:
1. Patients requiring chronic prophylactic usage of antibiotics
2. Patients, receiving any therapy that suppresses their immune system, such as a prolonged steroid usage, radiation or chemotherapy
3. Patients with medical history of bleeding disorders, of renal failures, of leucocyte dysfunctions or deficiencies
4. Patients with metabolic bone or uncontrolled endocrine disorders
5. Patients with craniofacial anomalies and/or physical handicaps that would interfere with the ability to perform adequate oral hygiene
6. Patients who participate in other studies requiring continuing investigational medication 7. Patients with alcohol and/or drug abuse
8. Female patients with a positive urine pregnancy test result

Local exclusion criteria:
1. Patients with inadequate oral hygiene
2. Occurrence of local inflammation, including untreated periodontitis
3. Mucosal diseases
4. History of local irradiation therapy
5. Presence of osseous lesions
6. Persistent intraoral infection
7. Lack of primary stability of the implant at surgery

Date of first enrolment
01/12/2006

Date of final enrolment
31/12/2011

Locations

Countries of recruitment

Germany

Study participating centre
Department of Orthodontics
Mainz
Germany
55131

Sponsor information

Organisation
Johannes Gutenberg University of Mainz (Germany)

Sponsor details
Langenbeckstr. 1
Mainz
Germany
55131

Sponsor type
University/education

Website
http://www-klinik.uni-mainz.de/

ROR
https://ror.org/023b0x485

Funder(s)

Funder type
Research organisation

Funder Name
The ITI Foundation for the Promotion of Oral Implantology (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/09/2007	05/01/2021	Yes	No
Interim results article		01/08/2011	19/07/2021	Yes	No