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The effects of customized dental implant healing caps on tissues around the implant

Submission date	Recruitment status	[_] Prospectively registered
28/01/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/05/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/12/2022	Oral Health	

Plain English summary of protocol

Background and study aims
Healing abutments (also called healing cuffs or caps) help the gum tissue around dental implants to heal. Frequent changes of healing abutments have been associated with negative effects on wound healing around the implant. The aim of this study is to compare the levels of markers of inflammation and tissue destruction around implants with customized and standard healing abutments.

Who can participate?
Patients with partial posterior edentulism, aged over 18 years, adequate bone quality and availabilty for implant placement, no signs of inflammation in the region where implant placement is planned, good systemic health conditions and stable occlusion

What does the study involve?
Implants are randomly allocated into one of two groups. One group of implants will be fitted with a one-piece titanium customized abutment after implant insertion. Control group implants will be fitted with standard healing abutments. Mouth fluid collection and x-rays will be carried out at suture removal at 1 week after implant placement, following crown delivery after 3 months, and at 6 months follow-up. Intraoral scanning will be performed to compare the changes in the soft tissue around the implant.

What are the possible benefits and risks of participating?
There are no risks expected for participants.

Where is the study run from?
Medical University of Vienna (Austria)

When is the study starting and how long is it expected to run for?
August 2017 to June 2022

Who is funding the study?
MIS Implants Technologies Ltd (UK)

Who is the main contact?
Dr Christian Wehner
christian.wehner@meduniwien.ac.at

Contact information

Type(s)
Principal Investigator

Contact name
Dr Christian Wehner

Contact details
Sensengasse 2a
Vienna
Austria
1090
+43 (0)1 40070 4720
christian.wehner@meduniwien.ac.at

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1807/2017

Study information

Scientific Title
Effects of customized CAD/CAM abutments on cytokine levels in peri-implant crevicular fluid during early implant healing: a pilot study

Study objectives
It is hypothesized that the use of customized healing abutments for dental implants induces an altered inflammatory response compared to standard healing abutments.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/09/2017, Ethics Committee of the Medical University of Vienna (Borschkegasse 8b /6, 1090 Vienna, Austria; +43(0)1 404 00 21470; ethik-kom@meduniwien.ac.at), ref: 1807/2017

Study design
Interventional single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Need for dental implant placement to replace missing tooth/teeth

Interventions
The aim of this exploratory randomized, controlled clinical trial is to assess the effect of one-piece individualized titanium abutments on biomarkers associated with inflammation and tissue degradation in peri-implant crevicular fluid (PICF) as well as marginal bone levels during the early healing phase.

The researchers plan to place a total of 30 dental implants in patients with partial posterior edentulism. Implant sites are randomized using online available tools (https://www.randomizer.org/) to either receive individual or standard healing abutments. 15 implants will receive a one-piece titanium abutment that will be fabricated using computer-aided design/computer-aided manufacturing (CAD/CAM) subsequently after implant insertion. Control group implants (n=15) will be provided with standard healing abutments. Peri-implant sulcus fluid collection, standardized periapical radiographs applying parallel technique and intraoral scanning will be carried out at suture removal 1 week after implant placement (T1), following crown delivery after 3 months (T2), and at 6 months follow-up (T3).

Intervention Type
Procedure/Surgery

Primary outcome measure
Peri-implant inflammation and tissue destruction measured by levels of biomarkers (pg/ml) in peri-implant crevicular fluid (PICF) at suture removal, at crown delivery and at 6 months follow-up

Secondary outcome measures
Marginal bone loss (mm) measured radiographically at suture removal, at crown delivery and at 6 months follow-up

Overall study start date
01/08/2017

Completion date
01/06/2022

Eligibility

Key inclusion criteria
1. Aged >18 years old
2. One or more missing teeth in the molar region of the upper and/or lower jaw
3. Adequate bone quality and availability for implant placement
4. No signs of inflammation in the region where implant placement is planned
5. Good systemic health conditions
6. Stable occlusion
7. Willing to participate and attend follow-up appointments

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
22

Total final enrolment
22

Key exclusion criteria
1. Presence of untreated periodontitis
2. Smokers (>10 cigarettes per day)
3. Alcoholism or drug abuse, history of chemotherapy or radiation
4. Diabetes with >7.5 HbA1c

Date of first enrolment
01/01/2019

Date of final enrolment
01/01/2022

Locations

Countries of recruitment
Austria

Study participating centre
University Clinic of Dentistry Vienna
Sensengasse 2a
Vienna
Austria
1090

Sponsor information

Organisation
Medical University of Vienna

Sponsor details
Sensengasse 2a
Vienna
Austria
1090
+43 (0)1 40070 2610
xiaohui.rausch-fan@meduniwien.ac.at

Sponsor type
University/education

ROR
https://ror.org/05n3x4p02

Funder(s)

Funder type
Industry

Funder Name
MIS Implants Technologies Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository at the Division of Conservative Dentistry, University Clinic of Dentistry, Medical University of Vienna. For further information please contact Dr Christian Wehner (christian.wehner@meduniwien.ac.at).

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			22/08/2022	No	No
Results article		24/12/2022	28/12/2022	Yes	No