DRKS-ID: **DRKS00018928**
Date of Registration in DRKS: **2019/12/02**
Date of Registration in Partner Registry or other Primary Registry: **[---]***

Deutsches Register Klinischer Studien
German Clinical Trials Register

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Augmented Reality in Oral & Maxillofacial Surgery: The Evaluation and application of an 3D glass in the clinical Oral and Maxillofacial Surgery

Trial Acronym

enFacedAR

URL of the trial

[---]*

Brief Summary in Lay Language

In this project, CT images of patients with mandibular or mid-face fractures, or PET/CT images from patients with head-neck tumors, will be displayed in an augmented reality environment (e.g. using the 3D glasses Microsoft Hololens®). The 3D visualization of the CT or PET/CT images will be examined by clinical experts (physicians) directly on and in relation to the patient. Medical image data will be acquired from the clinical routine, specifically from patients who underwent a CT or PET/CT scan because of a medical indication. Afterwards, the application and the possible benefit of this technology for the clinical domain will be evaluated with several clinical experts and questionnaires.
Hence, the aim of this observational study is a clinical evaluation of augmented reality (e.g. with a 3D glass) in the area of cranio-maxillofacial surgery. The evaluation will be based on clinical CT and PET/CT data.

Brief Summary in Scientific Language

In this project, CT images of patients with mandibular or mid-face fractures, or PET/CT images from patients with head-neck tumors, will be displayed in an augmented reality environment (e.g. using the 3D glasses Microsoft Hololens®). The 3D visualization of the CT or PET/CT images will be examined by clinical experts (physicians) directly on and in relation to the patient. Medical image data will be acquired from the clinical routine, specifically from patients who underwent a CT or PET/CT scan because of a medical indication. Afterwards, the application and the possible benefit of this technology for the clinical domain will be evaluated with several clinical experts and questionnaires.
Hence, the aim of this observational study is a clinical evaluation of augmented reality (e.g. with a 3D glass) in the area of cranio-maxillofacial surgery. The evaluation will be based on clinical CT and PET/CT data.

Do you plan to share individual participant data with other researchers?

Yes

Description IPD sharing plan

We will provide PET-CT datasets

Organizational Data

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- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **31-416 ex 18/19 , Ethikkommission der Medizinischen Universität Graz**

Secondary IDs

Health condition or Problem studied

- ICD10: **S02 - Fracture of skull and facial bones**
- ICD10: **M85 - Other disorders of bone density and structure**
- ICD10: **Q75 - Other congenital malformations of skull and face bones**
- ICD10: **S09 - Other and unspecified injuries of head**
- ICD10: **K10 - Other diseases of jaws**
- ICD10: **K07 - Dentofacial anomalies [including malocclusion]**
- ICD10: **Z96 - Presence of other functional implants**

Interventions/Observational Groups

- Arm 1: **Clinical evaluation of Augmented Reality in the facial/head area. Assessment/evaluation via two ISO questionnaire.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Other**
- Blinding: **[---]***

Study Type: **Non-interventional**

Study Type Non-Interventional: **Observational study**

Allocation: **Other**

Blinding: **[---]***

- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Diagnostic**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

ISO 9241/110 Questionnaire: Outcome is a score between 1 and 5, which will be acquired at the end of the experiments.

Secondary Outcome

ISONORM 9241/10 Questionnaire: Outcome is a score between 1 and 5, which will be acquired at the end of the experiments.

Countries of recruitment

- AT **Austria**

Locations of Recruitment

- University Medical Center **Medizinische Universität Graz,, Graz**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/07/31**
- Target Sample Size: **50**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **99 Years**

Additional Inclusion Criteria

Dentulous and/or edentulous jaws, men and women (women also of childbearing age), age ≥ 18, CT data acquired on the basis of medical diagnosis from the clinical routine in the Department of Oral and Maxillofacial Surgery at the Medical University of Graz, patients and CT data with a fracture of at least one bone in the cranio-maxillofacial complex, patients and PET/CT data from tumors in the head and neck/cranio-maxillofacial area.

Exclusion criteria

Existing Implants or osteosynthesis material, Age <18 Years, Lower jawbone necrosis or pathologic-cystic changes of the bones. Pregnant women.

Addresses

- **Primary Sponsor**

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  Austria

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  Fax: **[---]***
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- **Contact for Scientific Queries**

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- **Collaborator, Other Address**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Telephone: **[---]***
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E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*