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3D printing and planning for orbital floor (bottom part of the eye socket) fractures

Submission date
12/03/2023

Recruitment status
Recruiting

Registration date
14/03/2023

Overall study status
Ongoing

Last Edited
14/03/2023

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
An orbital floor fracture is a type of facial fracture that affects the floor or bottom part of the eye socket (orbit). The orbit is made up of several bones, including the maxilla, zygomatic, and frontal bones, which protect the eye and its surrounding structures.
Fixing a broken orbital floor can be hard because of how complicated its structure is and how difficult it is to get to. The best way to treat it in grown-ups is by using a titanium mesh to fix it through open surgery. With new 3D printing technology, doctors can plan the surgery better before they start, which is especially useful if they can't use a CT scan or navigation during the surgery. This study aims to see if using 3D printing and planning made treating orbital floor fractures more successful than not using it.

Who can participate?
Adult patients with isolated orbital floor fractures, who are administrated in P. Stradins Clinical University hospital in Latvia.

What does the study involve?
In this study, 3D-printed models of the eye socket will be used to help with surgery. The doctors will use the model to guide them as they bend a piece of titanium mesh to fit in the patient's eye socket. They will then perform surgery to repair the broken bone in the eye socket using the pre-bent titanium mesh. They will take a CT scan before and after the surgery to check the results. They will also ask the patient to evaluate their vision after the surgery, after 1 week, after 2 months, and after 6 months. A measurement tool will be used to analyze the size of the eye socket before and after the surgery.

What are the possible benefits and risks of participating?
Possible benefits of participating - more precise surgery, faster recovery, and undisturbed quality of life. Risks - as any other surgery.

Where is the study run from?
Riga Stradins University, Institute of Stomatology (Baltic biomaterials centre of excellence) and P. Stradins Clinical University Hospital (Latvia)

When is the study starting and how long is it expected to run for?
January 2022 to December 2026

Who is funding the study?
Riga Stradins University and RSU Institute of Stomatology (Latvia)

Who is the main contact?
Ieva Bagante (MD, DDS, PhD), Ieva.Bagante@rsu.lv

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2-PEK-4/132/2022

Study information

Scientific Title
3D printing and planning for surgery of orbital floor fractures in adult patients to improve patient related outcome. A comparison with retrospective patients group with orbital floor fracture reconstruction without 3D printing and planning

Acronym

3D OFF

Study objectives
3D printing and planning of orbital floor fractures gives higher success rate and faster recovery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/03/2022, Research Ethics Committee of Riga Stradins University (Riga Stradins University Main building Dzirciema 16 street, Riga, Latvia, LV-1007; +371 26691306; pek@rsu.lv), ref: Nr. 2-PĒK-4/132/2022

Study design
Single centre cross-sectional cohort study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files (in Latvian)

Health condition(s) or problem(s) studied
3D printing and planning for orbital floor fractures

Interventions
All consecutive adult patients with isolated orbital floor fracture were included in the study. CT scan before and after surgery. 3D printing and planning before surgery + pre bended implant (printed patient specific implant). Orbital floor reconstruction with pre-bended titanium mesh (standard procedure).
Orbital volume measurement before and after surgery.
Clinical diplopia evaluation after 1 week, after 2 months, after 6 months (if persistent)
To compare data with control group (patients' CT scan after surgery without 3D planning), orbital volume and success rate (repeated intervention, persistent diplopia).
To compare late clinical outcome with questionnaire at least 6 months after surgery.

Intervention Type
Procedure/Surgery

Primary outcome measure

Orbital volume changes were measured before and after repairment and compared with intact orbit. Measurements was preformed using 3D slicer image Computing Platform for the Quantitative Image Network

Secondary outcome measures
Clinical diplopia evaluation after 1 week, after 2 months, and after 6 months (if persistent) using a questionnaire with a visual analogue scale

Overall study start date
01/01/2022

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. All consecutive adult patients with isolated orbital floor fracture, who were treated in P. Stradins Clinical University hospital from 01/01/2022
2. Residents of Latvia

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Non residents of Latvia, e.g. refugees
2. Additional facial fractures e.g. zygomatic bone fractures
3. Poor quality CT scan
4. Missing CT scan
5. Not attended control visits
6. Mentally disabled patients
7. Children

Date of first enrolment
09/03/2022

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
Latvia

Study participating centre
P. Stradins Clinical University hospital
Pilsonu street 13
Riga
Latvia
LV-1007

Study participating centre
Riga Stradins University Institute of Stomatology
Dzirciema street 20
Riga
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LV-1007

Sponsor information

Organisation
Riga Stradiņš University

Sponsor details
Dzirciema 16
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Latvia
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+371 67062711
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Sponsor type
University/education

Website
http://www.rsu.lv/eng/

ROR
https://ror.org/03nadks56

Funder(s)

Funder type
University/education

Funder Name
Rīgas Stradiņa Universitāte

Alternative Name(s)
Rīga Stradiņš University, Rīga Stradiņš University, Universitas Rigensis Stradina, Riga Medical Institute, Medical Academy of Latvia, RSU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Latvia

Results and Publications

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

Intention to publish date
31/12/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request
Ieva Bagante, Ieva.Bagante@rsu.lv

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Latvian		14/03/2023	No	Yes
Protocol file			14/03/2023	No	No