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Blood-derived biomaterial for lower jaw surgery

Submission date 11/05/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/05/2024	**Overall study status** Completed	
Last Edited 04/08/2025	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
Orthognathic surgery is a common treatment approach for severe dentofacial deformities, which is done for repositioning the jaws when there is an incorrect position, shape, or size of the jaw. After large mandibular (jaw) movement during bilateral sagittal split osteotomy (BSSO) surgery, insufficient bone contact may result in compromised bone healing. Injectable platelet-rich fibrin (PRF) can be made from the patient's own blood to stimulate bone formation. The study aims to evaluate the use of PRF in orthognathic surgery in comparison to conventional orthognathic surgery.

Who can participate?
Patients aged 18-50 years with diagnosed dentofacial deformities who are undergoing bilateral sagittal split osteotomy (BSSO) surgery

What does the study involve?
Patients are assigned randomly to one of two groups – the study group and the control group. Control group patients undergo conventional BSSO. Study group patients provide blood samples 1-2 days before surgery for i-PRF preparation and laboratory analysis. Study group patients undergo BSSO, but during surgery prepared i-PRF is applied. At 7-12 days and 1 year after surgery all patients undergo CT scans.

What are the possible benefits and risks of participating?
The use of i-PRF can lead to improved surgical results leading to improved aesthetic results and patient satisfaction with surgery.
The researchers do not expect any significant risks as i-PRF is made from the patient's own blood.

Where is the study run from?
Riga Stradins University Institute of Stomatology (Latvia)

When is the study starting and how long is it expected to run for?
July 2020 to March 2025

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

Who is the main contact?
Dr Lana Micko, lana.micko@gmail.com, lana.micko@rsu.lv, lana.micko@rsusi.lv

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nr. 6-1/09/8

Study information

Scientific Title
Evaluation of platelet-rich fibrin effectiveness in contour defect modelling in orthognathic surgery

Study objectives
The use of platelet-rich fibrin (PRF) promotes newly formed bone volume increase in orthognathic surgery contour defect sites in comparison to conventional orthognathic surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/09/2020, Riga Stradins University Research Ethics Committee (Dzirciema iela 16, Riga, LV-1007, Latvia; +371 (0)67061547; pek@rsu.lv), ref: Nr. 6-1/09/8

Study design
Single-center interventional study randomized controlled trial.

Primary study design
Interventional

Study type(s)
Prevention, Efficacy

Health condition(s) or problem(s) studied
Prevention of mandibular lower border defects after bilateral sagittal split osteotomy

Interventions
Patients are randomly allocated to study and control groups by stratified randomisation method using a computer program. Patients know their allocated groups.

Before surgery, peripheral venous blood samples were collected from study group patients. Blood samples are used to prepare i-PRF using centrifugation for further i-PRF testing in the laboratory. ELISA assays are used according to the protocol to find the concentration of EGF, VEGF, PDGF, TGF1, and IL-8 in i-PRF. i-PRF samples are also used for anti-microbial tests against different microorganisms.

Bilateral sagittal split osteotomy (BSSO) surgery is carried out for control and study group patients. Study group patients during the surgery receive i-PRF, applied in osteotomy sites, i-PRF is prepared during the surgery from patients' venous blood samples.

1-2 weeks after surgery surgical results are evaluated using cone-beam computed tomography (CBCT). CBCT is also done 1 year after the surgery. Both CBCTs are analyzed using digital subtraction analysis and newly formed bone volume is measured at the vertical osteotomy site.

After all data is obtained statistical analysis is done.

Intervention Type
Other

Primary outcome(s)
1. Presence/absence of inferior border bone defects at the mandible near the vertical osteotomy site measured using CBCT at 1 year after surgery
2. Newly formed bone volume at the site of BSSO vertical osteotomy site measured using CBCT at 7-12 days and 1 year after orthognathic surgery

Key secondary outcome(s))
1. Bone resorption/remodelling near the osteotomy site measured using CBCT at 7-12 days and 1 year after surgery
2. Concentration of proteins in i-PRF and their correlation at 1-2 days before surgery:
2.1. EGF (pg/ml) measured using ELISA assay
2.2. VEGF (pg/ml) measured using ELISA assay
2.3. PDGF (pg/ml) measured using ELISA assay
2.4. TGFb1 (pg/ml) measured using ELISA assay

2.5. IL8 (pg/ml) measured using ELISA assay
3. The anti-microbial effect of i-PRF measured using the agar-diffusion method, zone of inhibition (mm) at 1-2 days before surgery

Completion date
03/03/2025

Eligibility

Key inclusion criteria
1. Aged 18-50 years
2. Patients diagnosed with dentofacial deformities, who were planned to undergo bilateral sagittal split osteotomy
3. A serum vitamin D level of more than 30 ng/ml is considered sufficient thereby patients were included in the study
4. Health condition - without any chronic disease, had no regular medication intake, had no abnormal nicotine or alcohol use

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
50 years

Sex
All

Total final enrolment
40

Key exclusion criteria
Patients who did not have cone-beam computed tomography 7-12 days and 1 year after surgery

Date of first enrolment
10/09/2020

Date of final enrolment
06/02/2024

Locations

Countries of recruitment
Latvia

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

Study participating centre
Pauls Stradins Clinical University Hospital
Pilsoņu iela 13
Riga
Latvia
LV-1002

Sponsor information

Organisation
Riga Stradiņš University

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

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon request from Dr Lana Micko (lana.micko@gmail.com; lana.micko@rsu.lv)
The type of data that will be shared: i-PRF obtaining and processing protocol for application in surgery, i-PRF obtaining and processing protocol for ELISA assay, and primary and secondary outcome measurements.
Dates of availability: 5 years after the end of the study.
Whether consent from participants was required and obtained: consent from study participants was required and obtained.
Comments on data anonymization: data are anonymized according to the European General Data Protection Regulation (GDPR).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/08/2025	04/08/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes