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Application of platelet-rich powder in combination with diode laser and piezo knife improves bone healing

Submission date
15/05/2023

Recruitment status
No longer recruiting

Registration date
08/06/2023

Overall study status
Completed

Last Edited
08/06/2023

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Patients with benign tumors, jaw cysts and other pathologies are admitted to the departments of maxillofacial surgery every year. The defect of the bone tissue remains after the surgery for these diseases, and according to the recommendations it is better to fill it in order to accelerate healing and rehabilitation and provide the possibility of dental implantation. Transplantation of bone substitute materials is widely used in clinical practice to treat bone deficiency in the maxillofacial region (mouth and jaws). Guided bone regeneration is a set of methods aimed at providing conditions for regenerative processes in bone tissue by introducing a source of regeneration into the defect. The aim of this study is to estimate the effectiveness of the use of platelet-rich powder (PRPP) to fill the bone cavity, which may reduce the cost of the procedure and eliminate the risk of allergic reactions.

Who can participate?
Patients aged 18 to 60 years who are undergoing surgery to remove cysts, benign bone formations of the jaw bones or impacted teeth (after the operation, bone defects were formed to be filled with a diameter of no more than 1.5 cm)

What does the study involve?
Participants are randomly allocated to one of two groups. The main group undergo surgical procedures with the use of PRPP, piezo knife and diode laser. The comparison group undergo implantation of osteoplastic (bone-forming) material in the bone defect after standard surgery with the use of a high-speed drill. Patients of the second group are also randomly allocated into three subgroups: comparison group A, where allogeneic (human) bone material is used; comparison group B where xenogenic (non-human) bone material is implanted; and comparison group C in which ß-tricalcium phosphate is used. In the control group the bone defect is filled with a blood clot and neither plasma powder nor any other osteoplastic material is used.

What are the possible benefits and risks of participating?
There will be no immediate direct benefits or risks to those taking part. Risks may be associated with the use of osteoplastic materials - allograft, xenograft, ß-tricalcium phosphate -where there

is a low risk of developing an allergic reaction, rejection or suppuration (pus discharge). To eliminate risks, monitoring is carried out in the postoperative period and dynamic monitoring throughout the year.

Where is the study run from?
S.D.Asfendyarov Kazakh National Medical University in Almaty (Kazakhstan)

When is the study starting and how long is it expected to run for?
July 2020 to May 2022

Who is funding the study?
The Ministry of Education and Science of the Republic of Kazakhstan

Who is the main contact?
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2. Dr Menzhanova Dana

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title

Application of platelet-rich powder, diode laser and piezosurgery device improves reparative osteogenesis

Study objectives
Application of platelet-rich powder (PRPP), diode laser and piezosurgery device improves reparative osteogenesis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/08/2020, Ethical Committee of Asfendiyarov Kazakh National Medical University (050000, Almaty, Tole bi str.92, 3rd floor, Kazakhstan; +8 (0)727 338 7024; lec.kaznmu@mail.ru), ref: 8(99)

Study design
Randomized clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients with post-surgical cavities (no more than 1.5 cm after cystectomy, benign bone tumor removal, impacted tooth extraction)

Interventions
The study was conducted among 200 patients aged 18 to 60 years who underwent surgery to remove cysts, benign bone formations of the jaw bones and extraction of impacted teeth (after the operation, bone defects were formed to be filled with a diameter of no more than 1.5 cm).

Participants were randomly assigned following simple randomization procedures (computerized random numbers) to one of two treatment groups. The main group included 80 patients, who underwent surgical procedures with the use of PRPP, piezo knife (NSK, Japan) and diode laser (Elexxion, Germany). The comparison group included 80 patients, who underwent implantation of osteoplastic material in bone defect after standard surgery with the use of high-speed drill (NSK, Japan). Patients of the second group were also randomly distributed into three subgroups: comparison group A (25 patients), where allogeneic bone material (SureOss, South Korea) was used; comparison group B (30 patients) where xenogenic bone material (BioOss, Switzerland) was imlanted; comparison group C (25 patients) in which ß-tricalcium phosphate (Sorbone, South Korea) was used. 40 patients formed a control group in which after surgery the bone defect was filled with a blood clot and neither plasma powder nor any other osteoplastic material was used.

To obtain PRPP, venous blood was taken in a volume of 36 ml, followed by centrifugation at an acceleration of 3500 rpm (1000 g) for 5 minutes. The second centrifugation was carried out after taking the plasma with a sterile syringe and transferring it to sterile test tubes with an acceleration of 1500 rpm (150 g) for 5 minutes. Platelet-rich plasma (PRP) was applied to a sterile glass or tray then it was dried in a thermostat for 7 minutes at a temperature of 40 °C. Then, using a sterile carvers, PRPP was collected from the surface of the material used. After

that PRPP immediately was applied during the surgical procedure to fill postoperative bone cavities in patients of the main group.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Reparative osteogenesis measured using bone trephine during dental implantation at 6 months after filling the bone cavities with PRPP or osteoplastic material
2. Bone healing measured using cone beam computed tomography (CBCT) with determination of bone density in the area of the filled bone defect and performed in Hounsfield units (HU) at 1, 3, 6, and 12 months

Key secondary outcome(s))
1. Local immunity and anti-inflammation effect of PRPP, measured by evaluation of pro- and anti-inflammatory cytokines (IL-1β, TNFα and IL-4) in the wound fluid with sandwich enzyme-linked immunosorbent assay on the 1st, 7th and 30th days after the operation
2. Wound healing (mucous healing) is measured using cytological analyses on days 1, 3, 5, 7, and 10 after the surgical procedure

Completion date
30/05/2022

Eligibility

Key inclusion criteria
1. Patients aged 18 to 60 years
2. Patients who underwent surgery to remove cysts, benign bone formations of the jaw bones and extraction of impacted teeth
3. After the operation, bone defects were formed to be filled with a diameter of no more than 1.5 cm

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
200

Key exclusion criteria
1. Pregnancy
2. Systemic diseases
3. After the operation, bone defects were formed to be filled with a diameter of more than 1.5 cm

Date of first enrolment
03/01/2021

Date of final enrolment
30/05/2021

Locations

Countries of recruitment
Kazakhstan

Study participating centre
Asfendyarov Kazakh National Medical University
Tole bi 92
Almaty
Kazakhstan
050000

Sponsor information

Organisation
Kazakh National Medical University

ROR
https://ror.org/05pc6w891

Funder(s)

Funder type
Government

Funder Name
Ministry of Education and Science of the Republic of Kazakhstan

Alternative Name(s)
Ministry of Education and Science, Republic of Kazakhstan

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Kazakhstan

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be stored in a non-publicity available repository of Asfendyarov Kazakh National medical university - https://stomatology.kaznmu.kz/научно-исследовательская-работа-6/

Among the participant-level data, only age and gender will be available, but not race and ethnicity. According to the agreement that is concluded with the Ministry of Education and Science for the conduct of the study, the fact that there is no need to indicate race and ethnicity is agreed, so in light of recent political events in Kazakhstan and neighboring countries it was recommended not to emphasize the possible difference between different ethnic groups and races.

IPD sharing plan summary
Stored in non-publicly available repository, Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes