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Effectiveness of corticosteroids in controlling complications after bichectomy surgery

Submission date
23/05/2023

Recruitment status
No longer recruiting

Registration date
27/07/2023

Overall study status
Completed

Last Edited
14/06/2023

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
Removal of fat within the cheeks (bichectomy of the adipose pouch of Bichat), aims to narrow the mid to lower part of the face. Maintaining a good quality of life during the postoperative period is desirable for both the patient and the surgeon. The administration of corticosteroids is one of the most commonly used interventions, due to their strong anti-inflammatory activity. However, there are no studies which report the use of submucosal injection of corticosteroids submucosal injection of corticoids in bichectomy surgery. Therefore, the objective of this research is to compare the effect of corticosteroid solution in a single dose, injected submucosally, versus no application, in the significant reduction of complications and quality of life measured in the first seven days after surgery in patients undergoing bichectomy surgery.

Who can participate?
Patients over 18 years old who want to have a bichectomy surgery in the dental clinic of Dr Pedro Aravena.

What does the study involve?
Participants will be randomly divided into 2 groups. The experimental group will be administered a single dose of 1 ml of betamethasone 4mg/ml with a submucosal injection in the buccal vestibule near the surgical site immediately after surgery and the control group will be administered 1 ml of 0.9% saline placebo.

What are the possible benefits and risks of participating?
There are no direct benefits to participating in this research. If, after analyzing the results, it is found that the procedure is safe and effective, other patients may benefit from these findings.

Participating in this research may expose the participant to a greater risk than not participating in this research. There is, for example, the risk that the drug may not control or decrease postoperative complications as well as would be liked. In that case, rescue medication will be used to alleviate those symptoms. Although the chance of this happening is very low, you should still be on guard for this possibility. The study team will try to decrease the chances of this occurring, but if something unexpected happens, the research team will be vigilant and responsible for any unforeseen events. There are also risks inherent to bichectomy surgery, such

as postoperative pain, swelling, edema, trismus, hematoma or, in more complex cases, infection of the wound with general malaise and fever. If such complaints occur, they should be reported to one of the three examiners for recommendations and also attend a private consultation to receive assistance.

Where is the study run from?
Dr Pedro Aravena Dental Clinic (Chile)

When is the study starting and how long is it expected to run for?
May 2022 to October 2023

Who is funding the study?
Universidad Austral de Chile (Chile)

Who is the main contact?
Dr Pedro Aravena, paravena@uach.cl (Chile)

Contact information

Type(s)
Scientific

Contact name
Dr Pedro Aravena

ORCID ID
https://orcid.org/0000-0003-1230-4573

Contact details
School of Dentistry Austral University of Chile
Rudloff Street #1640
Valdivia
Chile
5110434
+56 999980727
paravena@uach.cl

Type(s)
Public

Contact name
Dr Pedro Aravena

Contact details
School of Dentistry Austral University of Chile
Rudloff Street #1640
Valdivia
Chile
5110434
+56 632221205
paravenat@gmail.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effectiveness of corticosteroids in the control of postoperative complications and quality of life in patients undergoing bichectomy surgery in patients undergoing bichectomy surgery. Randomized clinical trial.

Study objectives
The application of corticosteroids in bichectomy surgery is effective in reducing postoperative complications and would not negatively affect the quality of life of patients

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/09/2022, Scientific Ethical Committee of the Valdivia Health Service (Comite Etico Cientifico Servicio de Salud Valdivia) (Provincia de Valdivia , Valdivia , 5090000, Chile; +56 (63) 228 1784; comiteeticocientifico@gmail.com), ref: 360/2022

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Dexamethasone submucosal injection

Interventions
This study aims to compare the efficacy of 1 ml of corticosteroid solution at a concentration of 4mg/mL betamethasone in a single dose, injected submucosally, versus no betamethasone application.

One hour before surgery, all patients will have been medicated with a dose of Amoxicillin 500 mg and Naproxen 550 mg and use of chlorhexidine digluconate mouthwash 0.12% (Oralgene, Maver Laboratory, Chile) for thirty seconds.

Randomisation: Patients are randomised into 2 groups, the intervention group will receive a single dose of steroid following surgery and the control group will receive a control solution.

A surgeon (surgery physician assistant) will perform the bichectomy surgery. For this, local anesthesia will be performed on the posterosuperior alveolar nerve and buccal nerve in the internal face of the cheek around the parotid excretory duct, depositing a solution of 1.8 mL (one cartridge) of Lidocaine 2% with Epinephrine 1:100,000 (Septocaine®. Saint-Maur des Fosses, Paris, France). After local anesthesia, the incision site will be located at the maximum opening of the mouth,1 cm posterior to the parotid excretory duct at the level of the occlusal face of the second upper molar. There a vertical incision of 1 cm in length is made with a scalpel blade nº 15 C until the bright yellow buccal fat pad that coincides with the content of the adipose pocket of the cheek is observed. Then using Kelly forceps, the fat will be avulsed in its content extending the blunt instrument towards the temporal and genian region until a mobile fat is obtained, taking care not to damage the vascular pedicle. The fat will be removed and the wound will be cleaned with 0.9% saline irrigation and hemostasis and wound closure with two 4.0 silk stitches (Ethicon. Johnson & Johnson, Texas, USA), indicating local compression with gauze. The assigned group will be administered a single dose of betamethasone 4mg/ml with a submucosal injection in the buccal vestibule near the surgical site, immediately after surgery and the other group will be administered 1 ml of 0.9% saline solution.

As postoperative indications, the use of Naproxen 550 mg every 8 hours for 3 days, a mouthwash of 10 mL of chlorhexidine digluconate 0.12% for 30 seconds, every 12 hours for 6 days and local compression of the cheeks with a local cold compress for one day will be indicated.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Dexamethasone (4mg/mL)

Primary outcome(s)
Postoperative complications, such as swelling, bleeding, ecchymosis, nausea, and food accumulation, as well as oral function and general patient activity, will be measured using the health-related quality of life Spanish version (HRQOL-sp) scale at baseline, 3, 5 and 7 days

Key secondary outcome(s))
Pain will be measured using the visual analog score (VAS) at baseline, 3, 5 and 7 days

Completion date
01/10/2023

Eligibility

Key inclusion criteria

1. Aged 18 years or older
2. Both sexes
3. Belonging to the ASA I classification of the American Society of Anesthesiologists

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
50

Key exclusion criteria
1. Patients consuming antibiotics, non-steroidal anti-inflammatory drugs or corticosteroids
2. Non-compliance with the protocol and the time required by the study

Date of first enrolment
01/06/2023

Date of final enrolment
01/07/2023

Locations

Countries of recruitment
Chile

Study participating centre
Austral University of Chile
Dental School, Faculty of Medicine, School of Dentistry
Valdivia
Chile
5110434

Sponsor information

Organisation
Austral University of Chile

ROR
https://ror.org/029ycp228

Funder(s)

Funder type
University/education

Funder Name
Universidad Austral de Chile

Alternative Name(s)
Austral University of Chile, UACh

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Chile

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Spanish		14/06/2023	No	Yes