

Assessing the effects of subperiosteal tunnels in rhinoplasty on post operative bruising and swelling

Submission date 01/10/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 01/10/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/11/2023	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Bruising and swelling are commonly associated with rhinoplasty (nose reshaping) and are the main factors that limit the return to daily activities. Several methods have been evaluated to minimize this, including the creation of subperiosteal tunnels, which involves raising the superficial vascular layer off the bone, preserving it from trauma during surgery. Our aim is to assess the efficacy of subperiosteal tunnels during rhinoplasty at reducing postoperative bruising and swelling.

Who can participate?

Men and women aged 17 years or older undergoing aesthetic rhinoplasty requiring bilateral osteotomies (cuts to the bony framework of the nose will need to be performed during surgery on both sides)

What does the study involve?

All patients will be undergoing rhinoplasty. They will be randomly allocated to have one side of their nose undergo subperiosteal tunnelling and one side to not (therefore all participants receive subperiosteal tunnelling, but the side that this will be done on is randomly assigned). 2 and 7 days post-surgery, bruising and swelling on each side of the nose will be assessed

What are the possible benefits and risks of participating?

Though the creation of subperiosteal tunnelling is widely performed, there is not much data on whether or not there is a reduction on bruising and swelling. The possible benefits could include less bruising/swelling post operatively on the side of the tunnelling . There are no added risks of surgery for participating subjects/

Where is the study run from?

Montreal Centre for Facial Plastic Surgery (Canada)

When is the study starting and how long is it expected to run for?

February 2015 to February 2017

Who is funding the study?
This study was investigator initiated and funded

Who is the main contact?
Dr Mark Samaha
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Contact information

Type(s)
Scientific

Contact name
Dr Mark Samaha

Contact details
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Additional identifiers

Protocol serial number
SPT

Study information

Scientific Title
Postoperative ecchymosis and edema following subperiosteal tunnels in rhinoplasty: a blinded randomised clinical trial

Study objectives
To assess the efficacy of subperiosteal tunnels prior to lateral osteotomies during rhinoplasty at reducing postoperative ecchymosis and edema.

Ethics approval required
Old ethics approval format

Ethics approval(s)
McGill University Faculty of Medicine Institutional Review Board, 10/05/2015, IRB Review Number A00-M17-15A

Study design
Interventional prospective single-centre matched-paired randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Post-operative ecchymosis and edema in rhinoplasty

Interventions

Subjects were randomly assigned to undergo subperiosteal tunneling on one side of the nose during rhinoplasty. The other side of the nose underwent rhinoplasty without the creation of tunnels. The randomisation process was done using Siri®, the voice activated virtual assistant on an Apple iPhone®, at the time of surgery. Siri® was asked to randomly select a number. If an even number was generated, the patient would undergo creation of subperiosteal tunnels prior to osteotomy in rhinoplasty on the right side. Patients were blinded to the side of the subperiosteal tunnels. Post operatively, 3 blinded evaluators were asked to grade the degree of ecchymosis and edema on each side of the face.

Intervention Type

Procedure/Surgery

Primary outcome(s)

The following are graded on a 0-10 visual analogue scale (VAS) 2 and 7 days after surgery:

1. Ecchymosis
2. Edema

Key secondary outcome(s)

N/A

Completion date

01/02/2017

Eligibility**Key inclusion criteria**

1. Age 17 years or older
2. Aesthetic rhinoplasty requiring bilateral osteotomies

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Rhinoplasty without ostetomies
2. Rhinoplasty with unilateral or intermediate osteotomy
3. Not willing to provide informed consent
4. 7 day follow-up not possible due to scheduling conflicts

Date of first enrolment

01/04/2015

Date of final enrolment

30/08/2015

Locations

Countries of recruitment

Canada

Study participating centre

Montreal Centre for Facial Plastic Surgery

1240 Beaumont, Suite 200

Montreal

Canada

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Sponsor information

Organisation

McGill University - Department of Otolaryngology Head & Neck Surgery, Division of Facial Plastic and Reconstructive Surgery

ROR

<https://ror.org/01pxwe438>

Funder(s)

Funder type

Not defined

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Mark Samaha (mark.samaha@mcgill.ca). Data will be available after publication, from approximately 01/01/2019 until 10/05/2022. The raw data included will be the grading of each participant on ecchymosis and edema by the evaluators on post-operative days 2 and 7. Access will be granted to researchers or institutions that could use our data for further evaluation of this surgical technique, for example for meta-analysis or a systematic review. Access will be granted by the PI (Dr Mark Samaha) upon request. Data will be anonymised by a numerical code and no patient identifiers will be used. Written consent has been obtained from the patients. There are no ethical or legal restrictions.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2019		Yes	No
Protocol file			21/11/2023	No	No