

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

<b>Submission date</b> 01/10/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 01/10/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/11/2023	<b>Condition category</b> 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  
mark.samaha@mcgill.ca

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Mark Samaha

**Contact details**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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)**

**Study design**

Interventional prospective single-centre matched-paired randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

**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 measure**

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

1. Ecchymosis
2. Edema

**Secondary outcome measures**

N/A

**Overall study start date**

01/02/2015

**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

## Age group

Adult

## Sex

Both

## Target number of participants

34

## Key exclusion criteria

1. Rhinoplasty without osteotomies
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

H3P 3E5

# Sponsor information

**Organisation**

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

**Sponsor details**

1001 Decarie Boulevard. Montreal, Quebec, Canada  
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**Sponsor type**

University/education

**ROR**

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

**Funder(s)****Funder type**

Not defined

**Funder Name**

Investigator initiated and funded

**Results and Publications****Publication and dissemination plan**

We intend to publish in JAMA Facial Plastics

**Intention to publish date**

30/11/2018

**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](mailto: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?
<a href="#">Results article</a>	results	01/03/2019		Yes	No
<a href="#">Protocol file</a>			21/11/2023	No	No