ISRCTN25350905 https://doi.org/10.1186/ISRCTN25350905

Topical use of adrenaline in different concentrations for endoscopic sinus surgery

Submission date 18/12/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/01/2008	**Overall study status** Completed	
Last Edited 10/03/2008	**Condition category** Ear, Nose and Throat	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Vasoconstrictors such as cocaine or epinephrine (adrenaline) are routinely applied during functional endoscopic sinus surgery. The goal is to control bleeding because, when surgery is endoscopic, even minor bleeding can be troublesome if it blocks the small end of the endoscope. Nevertheless vasoconstrictors might cause an increase in blood pressure and heart arrhythmias. The ideal adrenaline concentration should be the one to provide optimal operative field with no cardiovascular side effects. Despite its routine use, that concentration is yet to be determined. Concentrations of adrenaline varying from 1:1000 to 1:200,000 have been used both topically and sub-mucosally. Many studies have used both adrenaline and cocaine, which makes it difficult to establish the individual role of each substance on the outcome. We have decided to work with adrenaline solutions applied only topically.

We study the effects of topical use of adrenaline solution on the nasal mucosa in three different concentrations on systemic absorption of the drug, blood pressure, heart rhythm, operative bleeding and operative time during endoscopic sinus surgery for nasal polyposis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the ethic committee of Federal University of Rio de Janeiro (UFRJ) on 24 November 2004 (ref: 207/04 CEP)

Study design
Randomised double-blind single-centre controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Nasal polyposis

Interventions
Patients were submitted to endoscopic sinus surgery under general anesthesia for treatment of nasal polyposis using different concentrations of adrenaline solution applied topically to the nasal mucosa.

Concentrations:
1. Adrenaline 1:2000 with lidocaine 1% (4 ml)
2. Adrenaline 1:10,000 with lidocaine 1% (4 ml)
3. Adrenaline 1:50,000 with lidocaine 1% (4 ml)

The control group consisted of patients submitted to tonsillectomies using the same anesthetic protocol as the study groups but without the use of adrenaline solution during surgery.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
adrenaline

Primary outcome measure
The following data were collected during surgery (No assessment was done post-operatively):
1. Variation of blood pressure during surgery (measured by non-invasive blood pressure measures every 3 minutes)
2. Variation of heart frequency during surgery (measured continuously by 12 lead ECG)
3. Development of heart arrythmias during surgery (measured continuously by 12 lead ECG)
4. Operative bleeding (measured both objectively by the amount of blood aspirated during the procedure and subjectively by visual-analogue scale from 01 = no bleeding to 10 = very high bleeding)
5. Variation of plasma levels of adrenaline measured by three blood samples obtained during each surgery
6. Operative time

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/03/2005

Completion date
28/02/2007

Eligibility

Key inclusion criteria
1. Be over 18 years old
2. Need elective endoscopic sinus surgery under general anesthesia for the treatment of nasal polyposis
3. Understand and give written consent to participate in the trial
4. To be classified as grade I or II according to the American Society of Anesthesiology classification of pre-operative assessment

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Patients legally incompetent or unable, for any reason, to read and sign a written consent form
2. Patients who withdraw their consent in any time during the course of the trial, even if they have signed the consent form
3. Patients with systemic hypertension, coronary diseases, heart arrythmia, coagulation disorders, collagen disorders, renal or liver insufficiency in any degree, previously diagnosed or detected during pre-operative assessment
4. Pregnant women
5. Patients who do not follow the trial protocol for any reason, unless it is related to the use of the adrenaline solution
6. Patients in use of a number of medications that might interfere with blood pressure or coagulaion, such as anti-inflammatory drugs, oral hypoglicemics, beta agonists, etc

Date of first enrolment
01/03/2005

Date of final enrolment
28/02/2007

Locations

Countries of recruitment
Brazil

Study participating centre
Praia de Botafogo, 422 / 1106
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Sponsor information

Organisation
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Sponsor type
University/education

ROR
https://ror.org/03490as77

Funder(s)

Funder type
University/education

Funder Name
Federal University of Rio de Janeiro (UFRJ) (Brazil)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration