

# Nasal airway obstruction study - NAIROS

<b>Submission date</b> 06/03/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 24/03/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/06/2025	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

A deviated septum is a condition where the thin wall separating the nostrils (nasal septum) is off-center or crooked (deviation). Most people only have a minor deviation, but it can lead to difficulty breathing, snoring and a blocked nose. A septoplasty is a type of operation that corrects a deviated septum by removing excess bone and cartilage to straighten the septum and nasal passages. Like any operation, there is a risk of complications. Most patients need to take at least 5 days off work or usual activities after the operation. Some patients seem not much better after the surgery. Practice varies around the country, and there is no good evidence about this operation or its alternatives, or about who might benefit most from treatment, to inform help patients and doctors decide when it should be carried out. The aim of this study is to compare the effectiveness septoplasty or non-surgical care (medical management), which consists of nasal sprays in the management of adults with deviated septums.

### Who can participate?

Adults with have a deviated septum.

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group are treated surgically using a septoplasty procedure. Those in the second group are given a six month supply of two different nasal sprays, each to use twice daily. At the start of the study and then again after six and 12 months, participants in both groups complete a number of questionnaire in order to assess their quality of life, nasal symptoms and how much they are using health care services as well as a test to measure how well they are breathing through their noses.

### What are the possible benefits and risks of participating?

Participants may benefit from improvement in symptoms of nasal blockage, sleep disturbance and congestion/headache if these symptoms are related to blocked nose due to a deviated septum. For participants who receive the nasal spray, there is a risk of bleeding or irritation in the nose. For those who receive surgery, there is a risk of general complications from surgery, including minor bleeding, discomfort (common), heavy bleeding, temporary numbness of central upper teeth, hole in the septum (perforation) and cosmetic change in the appearance of nose (rare).

Where is the study run from?

Freeman Hospital (lead centre) and 15 other NHS hospitals in England, Scotland and Wales (UK)

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

March 2017 to June 2021

Who is funding the study?

National Institute for Health Research, Health Technology Assessment Programme (UK)

Who is the main contact?

1. Dr Sean Carrie (scientific)
  2. Dr Katherine Rennie (public)
- nairos.trial@newcastle.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Dr Sean Carrie

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### Type(s)

Public

### Contact name

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## Additional identifiers

## Clinical Trials Information System (CTIS)

2017-000893-12

### Protocol serial number

8302

## Study information

### Scientific Title

Multicentre RCT to determine the clinical and cost effectiveness of septoplasty compared with non-surgical strategy in the management of nasal septal deviation in adult patients with nasal airway obstruction in the presence of a deviated nasal septum, what is effectiveness of septal surgery with turbinate reduction compared with 6 months' topical nasal treatment in improving nasal symptoms

### Acronym

NAIROS

### Study objectives

The aim of this study is to determine whether and to what extent septoplasty is superior to medical treatment in the management of adult patients with nasal obstruction in the presence of a septal deviation.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

North East – Newcastle & North Tyneside 2 Research Ethics Committee, 31/08/2017, ref: 17/NE/0239

### Study design

Multi-centre randomized controlled trial with qualitative process and economic evaluation

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Deviated septum

### Interventions

Patients will be randomised to one of two groups in a 1:1 ratio using a variable block stratified design stratified by severity (baseline self-report NOSE category – moderate 30-50; Severe 55-75; extreme 80-100) and gender.

Surgery: Participants will undergo septoplasty and turbinate reduction

Medical management: Participants receive medical management, which will comprise of regular use of a nasal saline spray (sterimar) followed by a fluorinated steroid spray Mometasone for 6 months.

All patients will be followed up at 6 and 12 months post randomisation.

### **Intervention Type**

Mixed

### **Primary outcome(s)**

Patient reported assessment of nasal and general symptoms is assessed using the SNOT 22 questionnaire (Sinonasal Outcome Test) at baseline, 6 and 12 months.

### **Key secondary outcome(s)**

1. Objective assessment nasal airflow is measured using rhinospirometry (nasal partitioning ratio and peak nasal airflow measurements) at baseline, 6 and 12 months
2. Quality of life is measured using the Short Form 36 Quality of Life Questionnaire at baseline, 6 and 12 months
3. Health utilisation is measured using a health utilisation questionnaire at baseline, 6 and 12 months

### **Completion date**

04/03/2021

## **Eligibility**

### **Key inclusion criteria**

1. Adults aged  $\geq 18$  years with a baseline NOSE score  $\geq 30$
2. Septal Deflection visible at naseondoscopy
3. Capacity to provide informed written consent and complete the study questionnaires.

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Total final enrolment**

378

### **Key exclusion criteria**

1. Patients <18 years
2. Patients with a baseline NOSE score <30
3. Any prior septal surgery
4. Systemic inflammatory disease
5. Granulomatosis with poly angiitis
6. Naseoscopic evidence of unrelated associated pathology eg. adenoid pad, septal perforation, chronic rhinosinusitis indicated by the presence of polyposis or pus
7. Intranasal recreational drug use
8. Breastfeeding, pregnancy or intended pregnancy
9. Bleeding diathesis
10. Therapeutic anticoagulation
11. Known adverse reactions to general anaesthesia
12. Immunocompromised patients

**Date of first enrolment**

01/09/2017

**Date of final enrolment**

31/01/2020

## **Locations**

**Countries of recruitment**

United Kingdom

England

Scotland

Wales

**Study participating centre**

**Freeman Hospital**

High Heaton

Newcastle Upon Tyne

United Kingdom

NE7 7DN

**Study participating centre**

**Aberdeen Royal Infirmary**

Foresterhill

Aberdeen

United Kingdom

AB25 2ZN

**Study participating centre**  
**Queen Elizabeth Hospital Birmingham**  
Mindelsohn Way  
Edgbaston  
Birmingham  
United Kingdom  
B15 2TH

**Study participating centre**  
**Bradford Royal Infirmary**  
Duckworth Lane  
Bradford  
United Kingdom  
BD9 6RJ

**Study participating centre**  
**Darlington Memorial Hospital**  
Hollyhurst Road  
Darlington  
United Kingdom  
DL3 6HX

**Study participating centre**  
**Ninewells Hospital**  
ENT Department (Ward 26)  
Dundee  
United Kingdom  
DD1 9SY

**Study participating centre**  
**Monklands Hospital**  
Monkscourt Avenue  
Airdrie  
United Kingdom  
ML6 OJS

**Study participating centre**  
**Leeds General Infirmary**  
Great George Street

Leeds  
United Kingdom  
LS1 3EX

**Study participating centre**  
**Aintree Hosptial**  
Lower Lane  
Liverpool  
United Kingdom  
L9 7AL

**Study participating centre**  
**Royal Gwent Hospital**  
Cardiff Road  
Newport  
United Kingdom  
NP20 2UB

**Study participating centre**  
**Cumberland Infirmary**  
Newtown Road  
Carlisle  
United Kingdom  
CA2 7HY

**Study participating centre**  
**Derriford Hospital**  
Derriford Road  
Plymouth  
United Kingdom  
PL6 8DH

**Study participating centre**  
**Salisbury District Hospital**  
Odstock Road  
Salisbury  
United Kingdom  
SP2 8BJ

**Study participating centre****Wrightington Hospital**

Hall Lane  
Appley Bridge  
Wigan  
United Kingdom  
WN6 9EP

**Study participating centre****Guy's Hospital**

Great Maze Pond  
London  
United Kingdom  
SE1 9RT

**Study participating centre****Norfolk and Norwich University Hospital**

Colney Lane  
Norwich  
United Kingdom  
NR4 7UY

**Sponsor information****Organisation**

Newcastle Upon Tyne NHS Foundation Trust

**ROR**

<https://ror.org/05p40t847>

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

Government

**Funder Name**

National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The current 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?
<a href="#">Results article</a>		18/10/2023	19/10/2023	Yes	No
<a href="#">Results article</a>		13/03/2024	13/03/2024	Yes	No
<a href="#">Results article</a>	Healthcare professionals' and patients' views and experiences of surgical and medical treatment for nasal obstruction: a qualitative interview study for a Nasal Airway Obstruction Study (NAIROS)	08/06/2025	09/06/2025	Yes	No
<a href="#">Protocol article</a>	protocol	13/02/2020	17/02/2020	Yes	No
<a href="#">Basic results</a>		17/12/2021	16/06/2022	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes