ISRCTN16168569 https://doi.org/10.1186/ISRCTN16168569

Nasal airway obstruction study - NAIROS

Submission date
06/03/2017

Recruitment status
No longer recruiting

Registration date
24/03/2017

Overall study status
Completed

Last Edited
09/06/2025

Condition category
Ear, Nose and Throat

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 (nasual 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)
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Study website
http://www.nairos.co.uk

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
2017-000893-12

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

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

Secondary outcome measures
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

Overall study start date
01/03/2017

Completion date
04/03/2021

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
378

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. Naseondoscopic evidence of unrelated associated pathology eg. adenoid pad, septal perforation, chronic rhinosinusitis indicated by the prescence 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
England

Scotland

United Kingdom

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

Sponsor details
Newcastle Joint Research Office
Regent Point
Regent Farm Road
Newcastle Upon Tyne
United Kingdom
NE3 3HD

Sponsor type
Research organisation

Website
http://www.newcastlejro.org.uk/

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

Publication and dissemination plan
Findings will be presented at international academic meetings and published in peer-reviewed journals. Publication of the results of the study will follow CONSORT guidelines for reporting clinical trials and NIHR guidance on communication research outcomes. Findings will also be distributed via ENTUK and ENT Scotland, and via primary care networks and conferences –

including meetings of the Royal College of General Practitioners. The Royal Society of Medicine's Sections also have a good track record of multidisciplinary meetings where the implications of NAIROS might usefully be discussed. The results will also be publicised in national media, with the aid of press releases from the Newcastle upon Tyne Hospitals Foundation Trust and Newcastle Universities. The domain name www.nairos.com has been purchases and will be used as a means of retaining stakeholder engagement and, thereafter, publicising the results.

Intention to publish date
31/10/2021

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?
Protocol article	protocol	13/02/2020	17/02/2020	Yes	No
Basic results		17/12/2021	16/06/2022	No	No
HRA research summary			28/06/2023	No	No
Results article		18/10/2023	19/10/2023	Yes	No
Results article		13/03/2024	13/03/2024	Yes	No
Results article	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