ISRCTN13373396 https://doi.org/10.1186/ISRCTN13373396

Assessing the feasibility of using nasal saline irrigation for managing acute sinusitis

Submission date
13/02/2019

Recruitment status
No longer recruiting

Registration date
11/06/2019

Overall study status
Completed

Last Edited
13/07/2021

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Acute sinus infections are one of the most common infections managed in primary care. Currently, GPs prescribe antibiotics to most patients presenting with sinusitis, the highest of any of the common acute infections presenting in adults, at over 90%. The trouble with prescribing for most people is that we are using antibiotics too much which is causing the bacteria to become resistant, which is likely to lead in the future to serious infections becoming untreatable from 'superbugs'. Alternatives to the initial management with antibiotics are needed. Previous studies have tried nasal irrigation using salt solution for colds but the studies are small and not conclusive. There have also been studies of nasal irrigation in chronic sinus infections which do show some benefit. A large study in chronic or recurrent sinusitis in primary care showed that most people can learn to do nasal irrigation with simple advice and a short video to show how it is done, find it acceptable and will keep doing it over several weeks. However, there was some evidence that the approach to help people use nasal irrigation could be made more effective, dealing with key barriers or difficulties more effectively. There have been no good studies of saline irrigation in acute sinusitis. The aim of this study is to find out whether using nasal saline irrigation for managing acute sinusitis reduces the use of antibiotics.

Who can participate?
Patients aged 18 - 65 with acute recurrent sinusitis

What does the study involve?
Participants are randomly allocated to either immediate antibiotics (current usual treatment in primary care) or advice to do nasal irrigation for up to 3 weeks with a 'back-up' or delayed antibiotic prescription (a prescription that can be used if the sinusitis does not settle). Participants fill out a daily symptom diary to see whether irrigation makes any difference to symptom severity, or to the duration of illness, and whether antibiotics were used. Participants who are happy to have further tests have a swab of the nose.

What are the possible benefits and risks of participating?
This study will provide evidence of recruitment and follow-up rates, and is also likely to provide preliminary evidence about whether antibiotic use is likely to be reduced, in order to provide sufficient evidence for a larger application for a full trial. The benefits are potentially a reduction

in antibiotic prescribing/use and help managing symptoms. For nasal irrigation there have been no serious side effects reported, the most common side effects being nasal stinging and sinus discomfort for some patients. If stinging occurs, participants will be advised to reduce the amount of salt in the saline mixture.

Where is the study run from?
1. University of Southampton (UK)
2. University of Bristol (UK)
3. University of Oxford (UK)

When is the study starting and how long is it expected to run for?
August 2018 to June 2021 (updated 04/02/2021, previously: July 2020)

Who is funding the study?
National Institute for Health Research School for Primary Care Research (UK)

Who is the main contact?
1. Tammy Thomas
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2. Prof. Paul Little
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Contact information

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
253414

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
V1 01/06/2018, 45580, IRAS 253414

Study information

Scientific Title
Saline Nasal Irrigation For acute Sinusitis (SNIFSII)

Acronym
SNIFSII

Study objectives
1. The null hypothesis is that there is no difference between antibiotic utilisation rates between the strategy of providing immediate antibiotics and the alternative strategy of nasal irrigation and a delayed antibiotic prescription.
2. The alternative hypothesis is there are lower antibiotic utilisation rates when using nasal irrigation and a delayed antibiotic prescription compared with providing an immediate antibiotic prescription.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 13/09/2019:
1. Approved 20/06/2019, London-Surrey NRES, Health Research Authority (Whitefriars, Level 3, Block B, HRA, BS1 2NT; +44 (0)207 104 8310; nrescommittee.secoast-surrey@nhs.net), ref: 19/LO/0620
2. Approved 21/06/2019, HRA and Health and Care Research Wales, ref: 19/LO/0620

Previous ethics approval:
Approval pending, Surrey NRES, Health Research Authority (Whitefriars, Level 3, Block B, HRA, BS1 2NT; Email: nrescommittee.secoast-surrey@nhs.net), REC ref: 19/LO/0620

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
Sinusitis - URTI

Interventions
Participants are randomised to either:
1. Immediate antibiotics (current usual treatment in primary care)
2. Advice to do nasal irrigation for up to 3 weeks with a 'back-up' or delayed antibiotic prescription (a prescription that can be used if the sinusitis does not settle)

Participants will fill out a daily symptom diary to see whether irrigation makes any difference to symptom severity, or to the duration of illness, and whether antibiotics were used. Participants who are happy to have further tests will have a swab of the nose.

Sample size:
Feasibility estimates: to estimate follow-up rates in each group between 65% and 80%, to be reasonably sure that the follow-up rate is not 50% in each group (i.e.95% confidence intervals of +/- 15%) then 41 per group are needed. The researchers also anticipate that it should be possible for the intervention group to achieve use of antibiotics of around 65% or less. To estimate this proportion with 95% confidence intervals of +/- 15% (i.e. that antibiotic use is 80% or less) 41 per group is also needed. To allow for loss to follow-up more than 100 patients are needed.

Feasibility:
The previous JAMA trial recruited 238 individuals/4 years with one RA (one centre), but recruitment is currently more challenging. The researchers therefore estimate that with one RA at the coordinating centre and P/T RAs in two other centres will allow them to recruit their target efficiently in 2 winter seasons.

Intervention Type
Behavioural

Primary outcome measure
1. Antibiotic use measured using patient-reported symptom diary, completed over four weeks or until symptoms resolve.
2. Duration of moderately bad symptoms measured using a validated symptom diary; variables (using 7-point Likert scales): nasal blockage, discharge, unpleasant taste/smell, facial pain, pain on bending, impaired activities, generally unwell, sleep disturbance. Completed over four weeks or until symptoms resolve.

Secondary outcome measures
1. Symptom duration until little/no problem, measured using patient-reported symptom diary, completed over four weeks or until symptoms resolve
2. Mean symptom score measured using patient-reported symptom diary, completed over four weeks or until symptoms resolve
3. Development of new/worsening symptoms measured using patient-reported symptom diary, completed over four weeks or until symptoms resolve
4. Health-related quality of life measured using EQ5D, completed over four weeks or until symptoms resolve
5. Reconsultations/resource use during the next month measured using patient note reviews conducted by staff at the surgeries

Overall study start date
01/08/2018

Completion date
30/06/2021

Eligibility

Key inclusion criteria
The researchers pragmatically define acute sinusitis as having sinus discomfort and at least 2 other symptoms (2 of: patient-reported nasal obstruction, patient-reported purulent nasal discharge, or pus seen in the nasal cavity on inspection by the clinician).
They do not propose using prior duration (e.g. the requirement for at least 7 days without improvement in the Canadian guidelines) since there is no good evidence for a particular cut-off, and their aim is to help people who are currently being treatment with antibiotics for sinusitis, many of whom present with 7 days.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

Key exclusion criteria
1. Inability to complete outcomes (reduced capacity: dementia, severe uncontrolled mental illness; terminal illness etc)
2. Head/neck cancer
3. HIV
4. Immune-suppressive treatment
5. Cystic fibrosis
6. Pregnancy/breastfeeding
7. Other nasal disorders e.g. polyps; poor gag/swallow reflexes

Date of first enrolment
01/08/2019

Date of final enrolment
31/05/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Southampton
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Study participating centre

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Sponsor type
University/education

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research School for Primary Care 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
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/07/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Paul Little (p.little @soton.ac.uk). Type of data: quantitative trial data. When the data will become available and for how long: at the end of the feasibility study so probably by June 2021. If a reasonable proposal is made to the PI (Prof. Little) the data will be made available; in the unlikely event of a request being declined the Board of the NIHR SPCR will be the arbiter. All participants were consented, data will be anonymised, 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?
Protocol file	version V1.2	09/05/2019	16/09/2019	No	No
HRA research summary			28/06/2023	No	No