

Steam inhalation and Nasal Irrigation For recurrent Sinusitis

Submission date 05/01/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/02/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/11/2017	Condition category Ear, Nose and Throat	<input type="checkbox"/> Individual participant data

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

Study information

Scientific Title

A primary care randomised controlled trial of nasal irrigation and steam inhalation for recurrent sinusitis

Acronym

SNIFS

Study objectives

Sinusitis is caused by the retention of sinus secretions creating a favourable milieu for infectious agents. This may be caused by:

1. Obstruction or narrowing of the sinus ostia by oedema or anatomical variants
2. Mucociliary dysfunction
3. Altered mucous composition with decreased elasticity or increased viscosity

Hypothesis:

1. Is nasal irrigation effective in reducing the symptoms of recurrent sinusitis?
2. Is steam inhalation effective in reducing the symptoms of recurrent sinusitis?
3. Is a combination of the two treatments more effective, of equal effectiveness or less effective than each of the individual treatments alone?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Southampton & South West Hampshire Research Ethics Committee (B), 05/07/2007, ref: 07/Q1704/69

Study design

Pragmatic randomised controlled 2 x 2 factorial 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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Sinusitis

Interventions

Treatment and follow-ups will be for a 6-month period.

Group 1. Daily nasal irrigation. Subjects will be asked to irrigate the nose (150 ml through each nostril) daily for 6 months. A neti pot will be provided to each subject and they will make their own buffered 2.0% saline irrigation solution every 1 to 2 days comprising 1 heaped teaspoon salt, on half teaspoon baking soda and 1 pint tap water. We have chosen this intervention based on the provisional evidence from the previous randomised controlled trial in primary care.

Group 2. Daily steam inhalation. Subjects will be asked to inhale steam for 5 minutes per day by placing a towel over the head over a bowl of recently boiled water. This intervention is chosen for its wide availability and ease of use rather than a particular device such as rhinotherm.

Group 3. Combined treatment group. Subjects will be asked to use both treatments daily, with nasal irrigation prior to steam. The feasibility phase will determine whether it is more feasible and acceptable for patients to do both interventions at the same time of day, and which order is preferable.

Group 4. Control group. Normal care.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Severity of symptoms assessed by the Rhinosinusitis Disability Index (RSDI). During the feasibility stage RSDI and Sino-Nasal Outcome Test-20 (SNOT-20) will be recorded. Both are validated self-completion outcome measures for sinusitis. RSDI was used for the previous primary care study. It is anticipated that RSDI will be the primary outcome measure for this trial. However, if SNOT-20 is shown in the feasibility stage to be more sensitive to change it will be adopted as the primary outcome measure. Timepoints of assessment: 3 and 6 months.

Secondary outcome measures

From self-completion questionnaires at baseline, 3 and 6 months:

1. Quality of life assessed by the EQ-5D
2. Severity of sinus symptoms assessed by a Single-Item Sinus-Symptom Severity Assessment (SIA)
3. Severity of upper respiratory symptoms (coryza, sore throat, cough, earache, feeling unwell, fever) using format previously validated by our group
4. Belief in the importance of antibiotics and seeing the doctor for sinusitis using validated Likert scales

From a daily diary for one week of the study period at 3 months:

5. Side effects of treatment (and also reported side effects for previous 3 months)

6. Compliance with irrigation/inhalation (to minimise reporting bias, patients will be given 'permission' not to perform the intervention)

7. Use of over the counter treatments (e.g., analgesics, decongestants)

From notes review at the end of the follow-up period (at 6 months):

8. Number of prescriptions for antibiotics for sinus-related symptoms

9. Number of prescriptions for antibiotics in total

10. Number of GP visits regarding sinus-related symptoms and for other respiratory symptoms

Overall study start date

01/12/2008

Completion date

10/07/2011

Eligibility

Key inclusion criteria

Patients (both males and females) aged 18-65 years with recurrent or chronic sinusitis. Patients will be identified from GPs' computerised notes: those who have presented to their GP with 2+ episodes of acute or 1+ episode of chronic sinusitis in the last 3 years, who report moderate to severe impact of sinusitis symptoms on the quality of life.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

Minimum of 220 and maximum of 316

Key exclusion criteria

1. Inability to complete outcome measures

2. Head and neck cancer

3. HIV

4. Immunosuppressive treatment

5. Cystic fibrosis

6. Pregnancy/breastfeeding

7. Other nasal disorders e.g., polyps or other defect obstructing sinus

8. Poor gag or swallow reflexes

Date of first enrolment

01/12/2008

Date of final enrolment

10/07/2011

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Southampton

Southampton

United Kingdom

SO16 5ST

Sponsor information

Organisation

University of Southampton (UK)

Sponsor details

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Legal Services

Highfield

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Sponsor type

University/education

Website

<http://www.southampton.ac.uk>

ROR

<https://ror.org/01ryk1543>

Funder(s)

Funder type

Government

Funder Name

Programme Grants for Applied Research (ref: RP-PG-0407-10098)

Alternative Name(s)

NIHR Programme Grants for Applied Research, PGfAR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/09/2016		Yes	No
Results article	nested qualitative interview study results	03/11/2017		Yes	No