ISRCTN88204146 https://doi.org/10.1186/ISRCTN88204146

Steam inhalation and Nasal Irrigation For recurrent Sinusitis

Submission date 05/01/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/02/2009	**Overall study status** Completed	
Last Edited 06/11/2017	**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

Sponsor ref: RSO 3493

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
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Sponsor information

Organisation
University of Southampton (UK)

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Sponsor type
University/education

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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