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Nasal irrigation with licorice extract to treat inflammation of the nose and sinuses

Submission date
13/02/2020

Recruitment status
No longer recruiting

Registration date
17/04/2020

Overall study status
Completed

Last Edited
14/12/2022

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Using nasal irrigation with a saline solution is often recommended by physicians to reduce symptoms of inflammation of the nose and sinuses. However, the effect of the procedure is not good enough and lasts for a short time. The salty, bitter taste after nasal irrigation often makes patients unwilling to use it as daily care. Additional medications, such as corticosteroid, have been proposed to enhance the effect of nasal irrigation, however, patients can be wary of using steroids.

Licorice, a very common natural material, and has been found to have anti-inflammatory and immunomodulatory effect. Its sweet taste and smell are generally well-liked. For this study, a nasal irrigant containing licorice extract was developed.

The aim of this study is to see if nasal irrigation with licorice extract is more effective than with saline.

Who can participate?
Adults with rhinitis or chronic rhinosinusitis

What does the study involve?
Participants will use either a licorice, corticosteriod or salt water nasal irrigation at home twice per day over 4 weeks. They will be assessed at the start, middle (2 weeks) and end (4 weeks) of the study for changes to their nose and sinus using a blood test, questionnaires and clinical examination.

What are the possible benefits and risks of participating?
Because we will teach those participants how to do nasal irrigation correctly by an expert before study, they will have the benefit to lean the skill for further nasal care. In addition, any kind of interventions (NILE, NICS or NIIS) would be supposed to improve their nasal symptoms by degrees. According to our preliminary study, nasal irrigation with licorice was considerably safe without significant side effect and only some irrigation-related adverse events, such as transient ear pain or stuff were encountered but those discomfort feelings could be self-limited in a short time.

Where is the study run from?
Chiayi Chang Gung Memorial Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
March 2018 to October 2021

Who is funding the study?
Chiayi Chang Gung Memorial Hospital (Taiwan)

Who is the main contact?
Dr Geng-He Chang
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPRPG6H0011

Study information

Scientific Title
Investigating the effect of nasal irrigation with isotonic saline and extract of licorice on treatment of chronic rhinitis and sinusitis

Acronym
NILE

Study objectives
The anti-inflammatory and immunomodulatory effects of licorice have been well-studied. We hypothesise that licorice will be a more effective nasal irrigant than saline

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/09/2018, the Chang Gung Medical Foundation Institutional Review Board (No. 199, Dunhua N. Rd., Songshan Dist., Taipei City 105, Taiwan (R.O.C.), troublefup6@cgmh.org.tw, 886-3-3196200 ext.3708), ref: 201800183A0C501A3.

Study design
Randomized parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
allergic rhinitis, non-allergic rhinitis, chronic rhinosinusitis with polyposis, chronic rhinosinusitis without polyposis, nasopharyngeal carcinoma post-radiotherapy complicated with sinusitis

Interventions
The study includes five patient groups
1. Allergic rhinitis
2. Non-allergic rhinitis
3. Chronic rhinosinusitis with polyposis
4. Chronic rhinosinusitis without polyposis
5. Nasopharyngeal carcinoma post-radiotherapy complicated with sinusitis.

AT recruitment, patient past medical records will be assessed to know if there is oral or intranasal antihistamine or steroid used one month before study (the enrollment should stop to use those medication for one month at least before study). Patient's history will be taken to know if there is experience of sinonasal sugery (ex: turbinoplasty, septoplasty, rhinoplasty, sinus surgery, skull base surgery, etc.) or radiotherapy for nasal cavity, sinus or nasopharyngeal malignancy. Additionally, total IgE level and specific allergen test (MAST) will be checked on every participant to facilitate us to classify those patients (ex: allergic rhinitis or non-allergic rhinitis).

The participants in each group will be assessed at baseline and randomized to receive one of the three following interventions.
1. Nasal irrigation with licorice extract (NILE)
2. Nasal irrigation with corticosteroid solution (NICS)
3. Nasal irrigation with isotonic saline solution (NIIS)

The intervention is performed by patients at home twice per day over 4 weeks.

Before the study, every participant will accept subjective evaluation with questionnaires, including the total symptom scores (TSS composed of rhinorrhea, pruritus, sneezing and blockage; none=0, mild=1, moderate=2, severe=3, summing scores range from 0 to 12), visual analogue scores (VAS) for rhinorrhea, pruritus, sneezing, blockage, postnasal drip and sleeping quality (0-100mm for each items) and
Sino-nasal Outcome Test (SNOT-22). In addition, every patient will be evaluated objectively by flexible nasopharyngoscopy with Lund-Kenndy scores (scores: 0-12) and acoustic rhinometry to analyze the nasal resistance. We will collect patients' nasal discharge for analysis of inflammatory cytokines at our laboratory. Participants will return to the outpatient department for two follow
up sessions during the intervention, at 2 weeks and 4 weeks. The above measurements will be done before the study and at 2 and 4 weeks of follow-up points.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Improvement in nasal obstruction measured by TSS (0-3), VAS (0-100) and SNOT22 at 0, 2 and 4 weeks
2. Improvement in rhinorrhea measured by TSS (0-3), VAS (0-100) and SNOT22 at 0, 2 and 4 weeks
3. Improvement in sneezing measured by TSS (0-3), VAS (0-100) and SNOT22 at 0, 2 and 4 weeks
4. Improvement in itchy nose measured by TSS (0-3), VAS (0-100) and SNOT22 at 0, 2 and 4 weeks
5. Improvement in postnasal drip measured by TSS (0-3), VAS (0-100) and SNOT22 at 0, 2 and 4 weeks
6. Improvement in sleep quality measured by TSS (0-3), VAS (0-100) and SNOT22 at 0, 2 and 4 weeks

Secondary outcome measures
1. Nasal condition measured by nasal endoscopic examination, which is scored by using Lund Kennedy endoscopic scoring system, at 0, 2 and 4 weeks
2. Nasal resistance measured using acoustic rhinometry at 0, 2 and 4 weeks
3. Analysis of cytokines in the nasal discharge at 0, 2 and 4 weeks

Overall study start date

01/03/2018

Completion date
31/10/2021

Eligibility

Key inclusion criteria
1. Diagnosis of allergic or non-allergic rhinitis
2. Diagnosis of chronic rhinosinusitis with or without nasal polyps

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
300 (20 participants for each intervention and thus each arm will enroll 60 cases and total of five arms will have 300 cases))

Total final enrolment
60

Key exclusion criteria
1. Aged <20 years
2. Antihistamine or corticosteroid (oral form or intranasal spray) use within 4 weeks of the intervention
3. Pregnancy
4. Planned sinonasal surgery within 4 weeks of the intervention
5. Allergy to licorice.

Date of first enrolment
04/12/2018

Date of final enrolment
30/04/2021

Locations

Countries of recruitment
Taiwan

Study participating centre

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Sponsor information

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Sponsor type
Hospital/treatment centre

Website
https://www1.cgmh.org.tw/branch/jia/index.htm

ROR
https://ror.org/04gy6pv35

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Chiayi Chang Gung Memorial Hospital

Alternative Name(s)
Chia-Yi Chang-Gong Memorial Hospital, Chang Gung Memorial Hospital, Chia-Yi

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Taiwan

Results and Publications

Publication and dissemination plan
This trial will run for 3 years (until 30/04/2021). If any patient group data collection is completed, we will analyze the part of data and publish it. The targets for publication would be journals of Chinese medicine, otolaryngology, and complementary and alternative medicine.

Intention to publish date
30/04/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Allergic rhinitis	15/07/2021	12/08/2022	Yes	No
Results article	investigating nasal polps in a small number of treated patients	29/11/2022	14/12/2022	Yes	No