Efficacy Of Nasal Irrigation With Combination of 0.9% NaCl and Binahong Extract (Anredera Cordifolia) 2,5% In Allergic Rhinitis

NCT Number:

NCT Number:
13 March 2023

Efficacy Of Nasal Irrigation With Combination of 0.9% NaCl and Binahong Extract (Anredera Cordifolia) 2,5% In Allergic Rhinitis

Background

The current management of RA includes education, reducing exposure to allergens, pharmacology, immunotherapy, and complementary (Linton et al., 2021). Clinical practice therapy guidelines were developed on Allergic Rhinitis and its Impact on Asthma (ARIA) through integrated social media, mobile health, and multidisciplinary services (Bousquet et al., 2019; Zhang et al., 2021). According to ARIA recommendations, therapy aims to control the symptoms that arise. However, 20% more patients are still symptomatic even though they have received adequate therapy according to treatment guidelines. To overcome this problem, in the 20th century, personalized medicine developed a therapeutic method that adapts individual patient characteristics with a genetic basis, immunology, and bio-psycho-social profiles as a dynamic process (Licari et al., 2019). This therapeutic approach aims to minimize side effects, increase therapeutic success, and develop into precision medicine. The target of therapy that is currently being developed is to modify the immune response to allergens and prevent disease development with a preventive approach, namely at the beginning of the process when the allergen attaches to the nasal mucosa (Agache & Akdis, 2019; Dubey et al., 2019).

A study of the 0.3% Binahong extract combination, which has an anti-inflammatory effect on 0.9% NaCl nasal wash therapy in adult allergic rhinitis patients, has never been done before. There is a potential role, together with physical and immunological mechanisms, to increase the efficacy of nasal washing. Based on the explanation above, it is necessary to research to determine the effect of a combination of 3% Binahong extract as a herbal medicine to increase the results of 0.9% NaCl nasal wash by assessing mRNA expression (IL-4, IL-6, IL-13, and TNF-α) as the primary outcome. Besides that, secondary outcome assessments are still carried out in clinical symptoms, quality of life, and nasal physiology, which researchers usually do to assess treatment in allergic rhinitis patients. Hopefully, this research will become a source of allergic rhinitis therapy and support the independence of drugs with natural ingredients.

Methods

This study was designed with the Consolidated Standards of Reporting Trials (CONSORT) guidelines by clearly stating the items that must be informed in RCT research reports to avoid bias. The research flow process will follow the flowchart guidelines of the enrollment, allocation, follow-up, and analysis phases (Schulz et al., 2011). This research is a quantitative experimental study with a single-blind parallel randomized controlled trial design to determine the results of intervention for 0.9% NaCl nasal irrigation therapy added with 3% Binahong extract compared to the control group 0.9% NaCl nasal irrigation therapy for two weeks in adult RA sufferers, which are schematically described as follows:

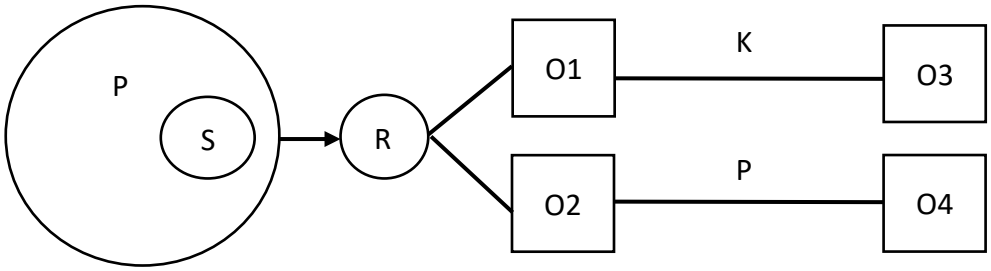

Figure 1. Research Design

Information:

P = Population

S = Sample

R = randomization of allocations

O1 = Examination before treatment

O2 = Examination before treatment

O3 = Examination after treatment

O4 = Examination after treatment

K = NaCl 0.9% nasal irrigation control

P = 0.9% NaCl nasal irrigation + 3% Binahong Extract

The process of randomization to allocate participants to the intervention group or control group was carried out using random numbers generated by a computer program and statistical software with an allocation of 1:1. The random number results were entered into sealed envelopes using the SNOSE (sequentially numbered, opaque sealed envelopes) system. Participants were assigned to the intervention or control group based on the order of randomization (allocation concealment) carried out by the research assistant and given a 0.9% NaCl nose irrigation pack plus 3% Binahong extract (freeze drying) or a 0.9% NaCl nose irrigation pack for two weeks. The investigators needed access to the blinding group's sequences, and the entire study team was instructed not to communicate with participants about their sequences.

The research sample was RA patients at the AMC Muhammadiyah General Hospital Polyclinic and PKU Muhammadiyah Gamping Hospital Yogyakarta who met the inclusion and exclusion criteria as follows:

1. Inclusion criteria
    a. Patients with RA symptoms (SFAR score≥7) (Widuri A, 2021), adult age (18 to 65 years), male or female
    b. SPT examination results are positive
    c. Agree to participate in the research (informed consent) in writing
2. Exclusion criteria
    a. Pregnant or breastfeeding women
    b. Active smoker
    c. Local allergic rhinitis
    d. Patients with autoimmune diseases
    e. Chronic rhinosinusitis with or without nasal polyps

The number of samples in this study was determined using the sample size formula for research that aims to determine the change in the average (mean) before and after the intervention of the two paired groups tested with paired t-test. The variables to be examined in this study are:

1. Independent variable: nasal washing treatment with 0.9% NaCl + 3% concentration of Binahong Extract or control nasal washing with 0.9% NaCl.

2. Dependent variables: mRNA expression (IL-4, IL-6, IL-13, and TNF-α), SNOT-22, Mini-RQLQ, Nasal flow and Patency, and Mucociliary Transport Time.
3. Control variables: gender, classification.

NCT Number:
13 March 2023

INFORMED CONSENT

We are, dr. Asti Widuri Sp. T.H.T.B.K.L., M.Kes, Dr. dr. Bambang Udji Djoko Rianto, Sp.T.H.T.B.K.L (K), M.Kes, Dr. dr. Luh Putu Lusy Indrawati, Sp.T.H.T.B.K.L (K), M.Kes, and dr. Didik Setyo Heriyanto, Ph.D., Sp.P.A (K), chaired by dr. Asti Widuri Sp. T.H.T.B.K.L., M.Kes from the Doctoral Study Program in Medicine and Health Sciences, University of Gadjah Mada, will conduct research entitled "Results of the Combination of NaCl 0.9% Nasal Wash with Binahong Extract (Anredera cordifolia) 2,5% in Allergic Rhinitis. Study of mRNA expression (IL-4, IL-6, IL-13, and TNF-α)".

This study aims to obtain scientific evidence of the benefits of adding Binahong extract in increasing the effectiveness of 0.9% NaCl nose wash in allergic rhinitis patients. The research team asks for your willingness to participate in this research. The research process requires the participation period of each participant for a maximum of months.

A. Voluntary participation in research

After receiving an explanation of the research process, you are free to choose whether to participate in this research without coercion. If you have decided to participate, if you change your mind one day, you can withdraw without being subject to fines or sanctions.

B. Research procedure

If you agree to participate in this research, the first stage is to ask you to sign two copies of the consent form, one submitted to the research team for archiving and the other for you to keep. The procedure to be carried out next is as follows:

1. Fill out the Score For Allergic Rhinitis (SFAR) questionnaire and undergo a Skin Prick Test (SPT) to determine whether you meet the diagnostic requirements as a participant.
2. If you meet the requirements, you will receive training on how to wash your nose from the research team.
3. You will undergo an examination to obtain primary data, including an ENT examination, filling out the SNOT-22 questionnaire, Mini-RQLQ, Mucociliary clearance examination, PNIF, and taking a nasal swab sample for PCR examination.

4. Obtain equipment and materials for washing the nose according to instructions and training, get WhatsApp chats to remind, and wash the nose twice daily for two consecutive weeks.
5. Undergo a re-examination, namely an ENT examination, filling out the SNOT-22 questionnaire, Mini-RQLQ, Mucociliary clearance examination, PNIF, and taking a nasal swab sample for PCR examination.
6. Report to the research team if there are complaints about the nasal washing therapy process via the form provided and WhatsApp chat, and you will be directed to a health facility.

C. Obligations of research subjects

As participants in this study, you must follow all the procedures described and written above. If something needs clarification, you are welcome to ask the research team.

D. Risks, side effects, and treatment

So far, the inspection procedure and nasal washing do not pose a risk of danger or side effects. However, Binahong extract has never been administered to the nasal cavity, so there is a possibility of irritation/allergic effects. If there are side effects of washing the nose (burning, itching, pain, earache, dizziness, nosebleeds), the procedure to be performed is as follows:

1. Report through the research assistant or research person in charge through the contact no provided.
2. Perform first aid by:
   a. Stop using nose wash.
   b. Avoid rubbing your nose.
   c. If you have a runny nose, wipe/absorb with a soft tissue.
   d. Steam therapy, by filling hot water in a basin and inhaling the steam.
   e. If you have pain, you can take pain relievers temporarily.
   f. If within 24 hours there is no improvement in symptoms, come immediately to the AMC Muhammadiyah Hospital Emergency Room or PKU Gamping Hospital Emergency Room to get treatment.

E. Benefits

The direct benefits are getting the skills to wash your nose safely, getting equipment and materials for washing your nose, get examinations and therapy according to indications for free.

F. Confidentiality

Research data will be stored for ten years, biological data in a locked cupboard, and electronic data will be accessed with a password. All information relating to the identity and illness of the father/mother/siblings will be kept confidential and kept by the research team. In contrast, the research analysis results will be published without mentioning the identity of the research subjects.

G. Compensation

You will receive compensation for transportation money when you come to the research location of IDR 50,000 for every attendance for inspection.

H. Financing

The researcher will bear all costs incurred related to the research with components: implementation of training, nasal washing equipment, materials, and medicines, as indicated.

I. Additional information

You are allowed to ask any unclear questions in connection with this research. If there are side effects from the nasal washing process and require an explanation, you can communicate with Dr. Asti Widuri Sp.THT-KL, M.Kes at 081392591972. You can also inquire about this research to the Medical and Health Research Ethics Committee, Faculty of Medicine UGM Tel (0274-588688 ext 17225 or +628112666869, email: mhrec_fmugm @ugm.ac.id.

NCT Number:
13 March 2023

INFORMED CONSENT

I, the undersigned, below:

Name : ……
Age : ……
Gender : ……
Address : ……
No.Phone : ……

I hereby this certify that I have received an explanation and the opportunity to ask about things I need to know about the research: "The results of the combination of 0.9% NaCl nose wash with 2.5% Binahong (Anredera cordifolia) extract in allergic rhinitis . Study of mRNA expression (IL-4, IL-6, IL-13, and TNF-α)". The explanation includes research procedures, examination procedures, objectives, benefits of examination, and therapy related to the research. The inspection procedures I will undergo include:

1. Fill in the identity, personal data, and written consent.
2. Answer the questions contained in the questionnaire given.
3. Come to the examination site at a predetermined time to fill out a questionnaire, undergo a nasal physiology examination, and (take a nasal swab) twice (first before nose washing therapy and secondly after nose washing therapy for two weeks).
4. Willing to receive daily WhatsApp reminders and perform nose washing for two weeks according to the instructions.
5. Report if something happens related to nasal washing therapy by filling out the form provided.

After obtaining this information, I declare that I voluntarily agree to participate in this research for the sake of research success.

Yogyakarta,……..

Researcher Respondent

(……) (……..)