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AYURVEDA MEDICAL COLLEGE
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TO WHOM SO EVER IT MAY CONCERN

This is to certify that the information in the attached documents is verified by me and is true to the best of my knowledge.

K.M.C.T. AYURVEDA MEDICAL COLLEGE * MANASSERY P.O. KOZHIKODE

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K.M.C.T. AYURVEDA
MEDICAL COLLEGE

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INNOVATION AND ENTREPRENEURSHIP DEVELOPMENT CENTRE

3.3.1
INSTITUTIONAL RESEARCH COMMITTEE

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INSTITUTIONAL RESEARCH COMMITTEE MEETING MINUTES – 16/10/2019

Venue – Seminar Hall

Members Prsesent

Si no	Name	Designation	Sign.
1.	Dr Dinesh Kumar	Chairperson	
2.	Dr T N Harikrishnan	Secretary	
3.	Dr Sarath K Babu	Member	
4.	Dr Adarsh	Member	
5.	Dr George P J	Member	

AGENDA - DISCUSSION OF SUBMITTED PROTOCOLS

The first meeting of 16/10/2019 after reconstitution was conducted

Four Protocols From Faculty Members were submitted for the research Committee approval . The committee has discussed & approved following Protocols. Forwarded to Institutional Ethical committee, medical college for further appraisal.

1. Evaluate the effect of specified Clinical yoga protocol on stress management of students studied NIT Kozhikode- A open clinical trial
   Dr Suresh V S , Dr Sanesh P B
2. Assessing the health status of preschool children in Karassery Tribal area after the flood attack
   Dr Subin, Dr Anjana R
3. Evaluate the effect of sathapushpa thaila in PCOS in adolescent girl of age group 15-22yrs

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INSTITUTIONAL RESEARCH COMMITTEE MEETING MINUTES – 23/10/2020

Webinar Meeting

Members Prsesent

Si no	Name	Designation	Sign.
1.	Dr Subhasree G H	Chairperson	
2.	Dr Sarath K Babu	Secretary	
3.	Dr Subin S	Member	
4.	Dr Vineetha	Member	
5.	Dr Sugeena	Member	
6.	Dr Alex	Member	

AGENDA - DISCUSSION OF SUBMITTED PROTOCOLS

Due to covid situation a webinar Meeting of research committee was constituted on 23/10/2020

Seven Protocols From Faculty Members were submitted for the research Committee approval . The committee has discussed & approved following Protocols.

1. Evaluate the effect of Tradaka on final year students of K M C T Ayurveda College undergoing online classes
   Dr Suresh V S , Dr Sijna V P
2. Role of Dasamoolakatuthrayam kashaya along with Sudharshanam tab for the prevention of covid attack inhealthy volunteers under the age group 25-45 yrs
   Dr Vineetha N , Dr Arathi V
3. Evaluate the effect of ayurvedic preventive protocol in the prevention of Covid 19

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INSTITUTIONAL RESEARCH COMMITTEE MEETING MINUTES – 19/11/2021

Venue – Seminar Hall

Members Prsesent

Si no	Name	Designation	Sign.
1.	Dr Subhasree G H	Chairperson	
2.	Dr T N Harikrishnan	Secretary	
3.	Dr Adarsh K	Member	
4.	Dr Subin S	Member	
5.	Dr Vipin P C	Member	
6.	Dr Nidhin V	Member	

AGENDA - DISCUSSION OF SUBMITTED PROTOCOLS

Research committee meeting was conducted on 19/11/2021 on the basis of ICMR Project notification. Protocols From all department were submitted for the research Committee approval. The committee has discussed & approved following Protocols. Forwarded to IEC Medical college for further reviewing

1. Evaluation of the Nephroprotective Activity & Therapeutic Potential of punarnavadhi kashayam in Chronic Kidney Disease.
   Dr Mridula , Dr Aparna
2. Literary Study of Collection and Analysis o Formulae Mentione in Vruhathraya and Laghutraya for Enhance the Memory
   Dr Ratheesh , Dr Rismiya
3. A survey on treatment modality for Amavata sandhi shotha (Rhematoid arthritis) in patience of K M C T Ayurveda College
   Dr Aswathi K Dr Asif Ameen
4. Technological yoga mat – Mr Jasir and Ms.Murshida irfana
5. Medicated Ayurvedic patches for instant pain relief - Mr Harikrishnan

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INSTITUTIONAL RESEARCH COMMITTEE MEETING MINUTES – 17/10/2022

Venue – Seminar Hall

Members Prsesent

Si no	Name	Designation	Sign.
1.	Dr Dinesh Kumar	Chairperson	
2.	Dr T N Harikrishnan	Secretary	
3.	Dr .Najeeb.T.K	Member	
4.	Dr.Sarun Mohan	Member	
5.	Dr .Archana Radhakrishnan	Member	

AGENDA - DISCUSSION OF SUBMITTED PROTOCOLS

The first meeting on17/10/2022 after reconstitution was conducted.
Seven Protocols From Faculty Members and students were submitted for the research Committee approval .
The committee has discussed & approved following Protocols and **forwarded to Institutional ethical committee for further appraisal.**

1. Evaluate the efficacy of Ayurbandhanam –wood cast based ayurvedic bandaging for fracture management - Amina shibila
2. Assessing the mental health status of people at oldage home 'santhwanam' in Mukkam.Dr Sarun Mohan, Dr.Aparna.T
3. Evaluate the effect of Shadbindhu thaila in Kaphaja sirasoola in college students of age group 19-23yrs.
   Dr.Sharon .P.Vals, Dr.Meenu P.R
4. Evaluate the effect of specified Clinical yoga protocol on OBESITY management in menopaused ladies-A open clinical trial
   Dr Sijna.V.P, Dr. Nayana

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INSTITUTIONAL RESEARCH COMMITTEE MEETING MINUTES 14/08/2023

Venue – Seminar Hall

Members Prsesent

Si no	Name	Designation	Sign.
1.	Dr .Subhasree G H	Chairperson	
2.	Dr .T N Harikrishnan	Secretary	
3.	Dr. Sarun Mohan	Member	
4.	Dr .Nidhin. V	Member	
5.	Dr .Archana Radhakrishnan	Member	

AGENDA - DISCUSSION OF SUBMITTED PROTOCOLS

The first meeting on 14/08/2023 after reconstitution was conducted. Four Protocols From Faculty Members were submitted for the research Committee approval . The committee has discussed & approved following Protocols and **forwarded to Institutional ethical committee for further appraisal.**

1. Efficacy and safety of ayurvedic interventions in iron defficiency anemia Dr.Nithin.V, Dr.Binju .K.T
2. Evaluate the effect of Jeeraka avaleha in the management of asrugdhra. Dr Aswathy Sara Varghese
3. Vamana followed by Darvyadi kashaya in the management of prediabetes.
   Dr.Arati.V, Dr Priyanka
4. Evaluate the effect of Brahmi swararsa as nasya in the management of dementia among working people aged between 40 -50 years old
   Dr Vineetha N, Dr Aparna T.

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Institutional Ethics Committee

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Reg.No.ECR/859/Inst/KL/2016

Ref. No.KMCT/RP 2023/IEC/31

APPROVAL OF RESEARCH PROJECT

The Institutional Ethics Committee, KMCT Medical College, Kozhikode has evaluated the protocol of the research project entitled.

"A CRITICAL STUDY ON THE ROLE OF PRAKRITI AND DIETARY HABITS IN THE MANIFESTATION OF AMLAPITTA WITH SPECIAL REFERENCE TO ACUTE GASTRITIS"

Submitted by Miss. Varna Das, IInd Professional BAMS Student KMCT Ayurveda Medical College, Kozhikode.

Guide: Dr Nidhin V, Associate Professor & HOD, Dept. of Roga Nidana , KMCT Ayurveda Medical College, Kozhikode.

The Committee has approved the same.

The investigator shall submit a copy of the completed research project to the Institutional Ethics Committee (IEC) immediately after the completion of the study.

14/11/23

SECRETARY

Dated : 14/11/2023

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
KMCT MEDICAL COLLEGE

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3.3.1
SUBMITTED SYNOPSIS

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PROJECT SYNOPSIS

TO BE SUBMITTED FOR:

CCRAS SPARK- 2023

TITLE

CRITICAL STUDY ON THE ROLE OF PRAKRITI AND DIETARY HABITS IN THE MANIFESTATION OF AMLAPITTA WITH SPECIAL REFERENCE TO ACUTE GASTRITIS

Guided by DR Nidhin V BAMS.MD

Associate Professor

Student: Ms Varna Das

Second year BAMS student

INTRODUCTION

Constitutional type of an individual or Prakriti is the basic clinical denominator in Ayurveda, which defines physical, physiological, and psychological traits of an individual and is the template for individualized diet, lifestyle counselling, and treatment[1]. The Pitta which undergoes Vidaha, increases in its amla property causing Amlapitta[2]. Amlapitta is one of the most common diseases seen in clinical practice. It is seen across all age group and class. Gastritis denotes an inflammatory process involving the wall of the stomach, particularly the mucosa due to various etiological factors[3]. The stomach normally secretes acid that is essential in the digestive process. Various factors including poor dietary and lifestyle habits contribute to the excess production of acid in the stomach which results in the condition known as Amlapitta or gastritis in modern parlance. Prakriti is a unique contribution of Ayurveda, which distinguishes the population into three main groups viz., Vata, Pitta and Kapha predominant individuals. Prakriti determines disease susceptibility as well as severity in a person[4]. Its assessment helps the physician to prescribe a suitable diet, daily regimen and lifestyle that can prevent non communicable diseases including Amlapitta[5]. Here an attempt is made through a sample survey to assess the role of prakriti and dietary habits in the progression and prognosis of Amlapitta with special reference to acute gastritis.

Keywords: Prakriti, Amlapitta, diet, acute gastritis

NEED FOR THE STUDY

Gastritis or inflammation of the gastric mucosa is a disease of global prevalence. Gastritis depending on the causes may be classified into acute gastritis and chronic gastritis. Chronic gastritis can be classified further into chronic superficial gastritis, atrophic gastritis, granulomatous gastritis and hyperplastic gastritis. In the majority of patients presenting with acute gastritis, the initial acute phase is subclinical and is of short duration (about 7 to 10 days). Acute gastritis also referred to as reactive gastritis occurs as a result of the trigger by factors such as NSAID's, Stress, bile reflux, radiation, Alcohol Abuse, cocaine addiction and ischemic damage[6].

Ayurveda identifies Amlapitta as a disease caused due to the increased Vidaha property of Pitta leading to sour taste or Amlatva[7]. The causes of Amlapitta may be categorised under Aharaja Hetu (dietary factors), Viharaja Hetu (habit factors), Manasika Hetu (psychogenic factors) and Agantuka Hetu (miscellaneous factors).

Prakriti of a person and dietary habits play a crucial role in manifestation and prognosis of a disease. Hence a deeper knowledge in the role of Prakriti and Dietary habits in Amlapitta can give further insight to the manifestation and management of Amlapitta. This study will also help in identifying the common phenotypes susceptible for Amlapitta and thereby help in preventive aspect of the disease.

REVIEW OF LITERATURE

- Deha Prakrti is mentioned extensively by Charaka, Susrutha and Vagbhata.
- In the Brihatrayi's and Lagutrayis there are references of Amlapitta in various contexts
- Kashyapa Samhita, Madhava Nidana and its commentators gives importance to Amlapitta and describes its aetiopathogenesis and symptomatology in detail along with two clinical subtypes i.e. Urdhvaga and Adhoga Amlapitta.
- Textbooks of medicine has detailed sessions on acute gastritis, its causes, classification, pathogenesis and management.

OBJECTIVES

1. To conduct a survey to evaluate role of prakriti based susceptibility in the manifestation and prognosis of Amlapitta

2. To evaluate role of dietary habits in the manifestation of Amlapitta

3. To critically analyse the relation between Amlapitta and acute gastritis

METHODOLOGY

A survey to be conducted involving 50 diagnosed cases of Amlapitta from the setting of either sex between the age group of 18-55 yrs. After explaining and obtaining the consent form from the patient, detailed questionnaire form will be applied to assess the Prakriti and diet habit of the patient. The self assessment questionnaire to assess Prakriti prepared by Kishor Ptwardhan and Rashmi Sharma will be used as the questionnaire form to assess Prakriti of the selected

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patient. A questionnaire based on current informations related to dietary habits in Amlapitta will be used to assess the dietary factors responsible in Amlapitta.

RESEARCH HYPOTHESIS (H1)

Prakrithi has significant influence on the onset, progression and severity of Amlapitta.

NULL HYPOTHESIS (H0)

Prakrithi has no significant role on the onset, prognosis and severity of Amlapitta.

INCLUSION CRITERIA

1. Patients of Amlapitta of either sex
2. Age group of 18-55ys

EXCLUSION CRITERIA

1. Patients with other diseases or comorbidities

MATERIALS AND METHODS

SOURCES OF DATA

Research Design & Approach	: FUNDAMENTAL RESEARCH
Setting of the study	: COLLEGE HOSPITAL
Target Population	: GENERAL PUBLIC OF EITHER SEX
Sampling Population	: PATIENTS OF AMLAPITTA
Sampling technique	: CONVINIENCE SAMPLING
Sample size	50

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ASSESMENT METHOD

A survey will be conducted on the selected patients using case format. questionnaires on prakriti assessment and dietary habits associated with Amlapitta.

DIAGNOSTIC CRITERIA FOR ASSESMENT OF AMLAPITTA

Tikta – Amlodgara (Sour and bitter belching). Hritkantha Daha (Heart and throat Burn) and Avipaka (indigestion) which are the cardinal features associated with Amlapitta will be considered to diagnose Amlapitta in the patient.

DIAGNOSTIC CRITERIA FOR ASSESMENT OF ACUTE GASTRITIS

There is no standardised diagnostic criteria and the diagnosis is usually made on medical history and physical examination. The common symptoms associated with acute gastritis are

- Stomach pain or discomfort
- Heartburn
- Loss of appetite
- Nausea
- Vomiting
- Fullness of abdomen

ETHICAL CONSIDERATION:

- The researcher will maintain the privacy & confidentiality of the data.

- Prior consent from patients will be collected in document form.

- Since this is a survey study and includes no interventions, ethical issues are not involved.

- A written permission from the Institutional head is obtained. regarding the ethical aspects.

Does the study require any investigation or intervention to be conducted on thepatients or on community people? If so please describe briefly.

No

Has Ethical Clearance been obtained from your institution in case of the above?

Yes, enclosed

IMPLICATION

- The data enables us to identify as a susceptible population for amla pitta. This helps to suggest a healthy lifestyle and food habits so as to prevent health issue related to Amlapitta
- The data can be used to asses the degree of severity and speed of progression of the disease among the people of Amlapitta.
- The concept of personalised healthcare in ayurveda needs a highlight in this era of OTC market and this data will substantiate the above finding.

REFERENCES

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2. Madhavakara , Madhava Nidana, Part 2nd, with Madhukosha Sanskrit commentary by Sri Sudarshan Sastri, 13th edition, Chaukhamba Sanskrit Sansthan, Varanasi, 2001, 51/3-4.
3. K V Krishnadas, Textbook of medicine, 6th edition, Vol 1, 2017, pg no 489
4. Agnivesha. Charaka samhita, English translation by Sharma RK, Dash B. Vol-1, Viman Sthan (6/16), Chaukhambha Sanskrit series office, Varanasi; 2010
5. K V Krishnadas, Textbook of medicine, 6th edition, Vol 1, 2017, pg no 490
6. K V Krishnadas, Textbook of medicine, 6th edition, Vol 1, 2017, pg no 490
7. Madhavakara , Madhava Nidana, Part 2nd, with Madhukosha Sanskrit commentary by Sri Sudarshan Sastri, 13th edition, Chaukhamba Sanskrit Sansthan, Varanasi, 2001, 51/3-4.

Title

Investigating the Efficacy and Safety of Ayurvedic Bronchodilator Inhaler in the Management of Respiratory Conditions: A Randomized Controlled Trial

Guided by DR Nidhin V BAMS.MD
Associate Professor

Student: Ms Varna Das
(Second year BAMS student)

1. Introduction

Ayurveda, an ancient system of medicine originating from India, offers a holistic approach to healthcare, including the management of respiratory conditions. While modern bronchodilator inhalers are widely used for conditions like asthma and chronic obstructive pulmonary disease (COPD), there is growing interest in exploring the efficacy and safety of Ayurvedic formulations as alternative or complementary treatments. As there is no ayurvedic bronchodilators in the form of inhalers available in the market we plan to introduce innovative interventions in the development of an ayurvedic inhaler which delivers drug directly to the target site. This proposal aims to conduct a randomized controlled trial to investigate the effectiveness of an Ayurvedic bronchodilator inhaler in improving respiratory symptoms and lung function among patients with respiratory conditions.

2. Objectives

- To evaluate the efficacy of the Ayurvedic bronchodilator inhaler in relieving symptoms of dyspnea, cough, and wheezing in patients with asthma or COPD.
- To assess the impact of the Ayurvedic inhaler on lung function parameters, including forced expiratory volume in one second (FEV1) and peak expiratory flow rate (PEFR).
- To examine the safety profile of the Ayurvedic inhaler, including adverse events and tolerability.
- To explore patient satisfaction, adherence, and preferences regarding the Ayurvedic bronchodilator inhaler compared to conventional bronchodilators.

3. Methodology

- Study Design: A randomized, double-blind, placebo-controlled trial will be conducted.
- Participants: 50 Patients diagnosed with asthma or COPD, aged 18-65 years, will be recruited from outpatient respiratory clinics.
- Intervention: Participants will be randomized to receive either the Ayurvedic bronchodilator inhaler or placebo inhaler, in addition to standard care. The Ayurvedic inhaler formulation will be prepared according to traditional Ayurvedic principles and will contain ingredients known for their bronchodilator properties.

Sno	Ayurvedic name	Scientific name	Major	Function

	of the plant		chemical content	
1	shirisha	*Albezia lebbeck*		Treating asthma, colds, cough and allergic diseases
2	nagaramotha	*Cyperus rotundus*	sesquiterpenoids	Antiinflammation Antioxidant
3	kanthakari	*Solanum xanthocarpum*		Bronchodilator Antimicrobial Antiinflamatory

S No	Ayurvedic name of plant	Scientific name	Major chemical content	Function
1	Sati	Hedychium spicatum	Sitosterol, cineole, terpinene	Vasodilator, anti-asthmatic, hypotensive properties
2	Pushkaramula	Inula racemose	Isoalantolactone, alantolactone,	Anti-inflammatory, anti-allergic, beta-adrenergic, receptor antagonist
3	Amlavetasa	Garcinia pedunculata	Phenolics, flavonoids, ascorbic acid	Anti-oxidant, anti hyperglycaemia, cardio protective
4	Ela	Elattaria cardamomum	Terpinene, stigmasterol, geraniol, borneol, bisabolene,	Anti-inflamatory, anti-spasmodic, anti-cancerous, analegiscs
5	Hingu	Ferula narthex	Umbelliferone, asaresinotannol, malic acid, resorcin, vanillin	Muscle relaxant, anti-hyperlipidemic, anti carcinogenic, anti-spasmodic
6	Agaru	Aquilaria agalocha	Benzylacetone, anisic acid, baimuxinic acid, agarol, agarospiral	Analgesic, membrane stabilizing action, anti-histaminic action
7	Surasa	Ocimum sanctum	Eugenol, urosolic acid, linalool, sitosterol,	Anti-histamine, immunomodulatory, anti inflamatory
8	Tamalaki	Phyllanthus amarus	Alkaloids, rutin, gallic acid, tannins, saponins	Anti-viral immuno-modulatory cardioprotective
9	Jivanti	Leptadenia reticulata	1-Dodecene,	Anti inflammatory

			Methyl-10-udecenoate, lupeol	anti microbial
10	Canda	Angelica glauca	Valeric acid, angelicin,	Anti-inflamatory Bronchodilator

S No	Ayurvedic name of plant	Scientific name	Major chemical content	Function
1	Sati	Hedychiumspicatum	Sitosterol, cineole, terpinene	Vasodilator, anti-asthmatic, hypotensive properties
2	Pushkaramula	Inula racemose	Isoalantolactone, alantolactone,	Anti-inflammatory, anti-allergic, beta-adrenergic, receptor antagonist
3	Tamalaki	Phyllanthus amarus	Alkaloids, rutin, gallic acid, tannins, saponins	Anti-viral immuno-modulatory cardioprotective
4	Hingu	Ferula narthex	Umbelliferone, asaresinotannol, malic acid, resorcin, vanillin	Muscle relaxant, anti-hyperlipidemic, anti carcinogenic, anti-spasmodic
5	Tulasi	Ocimum tenuiflorum	Linalool, eunol, methylcinnamat, ocimene,pinene, thymol, citral, camphor	Anti-inflammatory, anti microbial, chemopreventive
6	Ela	Elattaria cardamomum	Terpinene, stigmasterol, geraniol, borneol, bisabolene,	Anti-inflamatory, anti-spasmodic, anti-cancerous, analegiscs

S No	Ayurvedic name of plant	Scientific name	Major chemical content	Function
1	Bilva	Aegle marmelos		
2	Agnimantha	Premna mucronate		
3	Shyonaka	Oroxylum indicum		
4	Patala	Stereospermum		

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		suaveolens		
5	Gambhari	Gmelina arborea		
6	Brihati	Solanum indicum		
7	kanthakari	*Solanum xanthocarpum*		Bronchodilator Antimicrobial Antiinflamatory
8	Gokshura	Tribulus terrestris		
9	Shalaparni	Desmodium gangeticum		
10	Prishnaparni	Uraria picta		

- Outcome Measures: Primary outcomes will include changes in respiratory symptoms (dyspnea, cough, wheezing) assessed using standardized questionnaires and lung function parameters measured through spirometry. Safety outcomes will include the incidence of adverse events and changes in vital signs. Patient satisfaction and adherence will be assessed using validated scales and questionnaires.
- Data Analysis: Statistical analysis will be performed to compare outcomes between the Ayurvedic and placebo groups. Subgroup analyses may be conducted based on disease severity and patient characteristics.

4. Expected Outcomes:

- Insights into the efficacy of the Ayurvedic bronchodilator inhaler in improving respiratory symptoms and lung function in patients with asthma or COPD.
- Assessment of the safety profile and tolerability of the Ayurvedic inhaler compared to placebo.
- Understanding patient preferences and satisfaction with the Ayurvedic bronchodilator inhaler as an alternative or adjunctive therapy.

5. Significance of the Study:

- This research will contribute to the evidence base for Ayurvedic interventions in respiratory medicine, potentially offering new treatment options for patients with asthma and COPD.
- Findings from this study can inform healthcare providers and patients about the potential benefits and risks of using Ayurvedic bronchodilator inhalers.
- The study may pave the way for further research into the integration of traditional medicine systems like Ayurveda into mainstream healthcare for respiratory conditions.

6. Timeline:

- Proposal Development: March-April 2024
- Ethics Approval and Participant Recruitment: May-June 2024
- Intervention and Data Collection: July-December 2024
- Data Analysis: January-February 2025
- Report Writing and Dissemination of Results: March-April 2025

7. Budget:

- The budget will include expenses for research personnel, study materials, participant recruitment, data collection, and statistical analysis.
- Funding sources may include grants from research institutions, government agencies, or pharmaceutical companies with an interest in traditional medicine.

8. Ethical Considerations:

- Informed consent will be obtained from all participants prior to enrollment in the study.
- The study protocol will be reviewed and approved by the appropriate ethics committee or institutional review board.
- Measures will be taken to ensure patient confidentiality and compliance with ethical guidelines throughout the study.

9. Conclusion:

This research proposal outlines a randomized controlled trial to investigate the efficacy and safety of an Ayurvedic bronchodilator inhaler in the management of respiratory conditions. By conducting rigorous scientific research, this study aims to provide valuable insights into the potential role of Ayurveda in respiratory medicine and offer evidence-based treatment options for patients with asthma and COPD.

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