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CLINICAL VALIDATION OF NIRGUDI OIL IN RHEUMATOID ARTHRITIS AN OPEN LABEL, PROSPECTIVE PILOT STUDY

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SUMMARY

Title: CLINICAL VALIDATION OF NIRGUDYADI OIL IN RHEUMATOID ARTHRITIS AN OPEN LABEL, PROSPECTIVE, PILOT STUDY

Study Period: 25th January 2018 – 15th April 2018

No. of study centers: 1

Objectives: To compare the efficacy and safety Nirgudyadi oil

Trial Design: Prospective single-blind,

Number of patients screened: 21

Number of patients enrolled: 15

Number of patients treated: 15

Methodology: The study was open labeled, prospective in patients with rheumatoid arthritis. The patients who are eligible to participate, by inclusion & exclusion criteria, have provided a written informed consent at the screening visit.

The study had a single treatment of Nirgudyadi oil.

Drug Review

Each 5ml oil contains

Nirgudi ext 1g

Camphor 0.2g

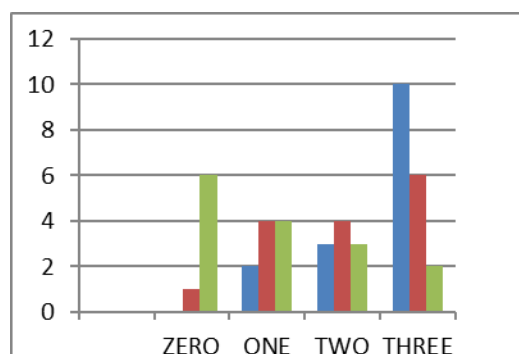
Vacha ext 0.2g

Shunthi root ext 0.1g

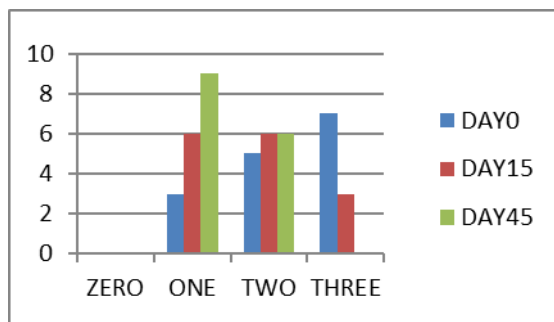
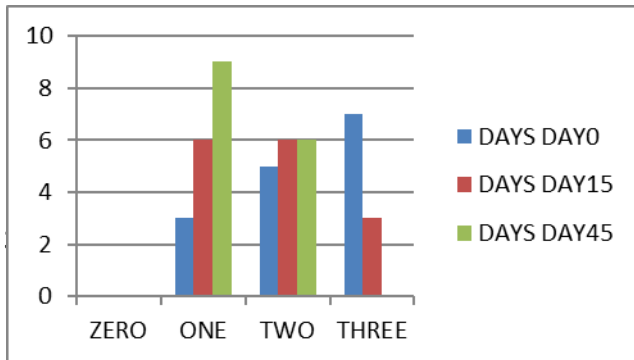
Seasam oil 3.5g

Statistical Analysis:

1 JOINT PAIN



2 MORNING STIFFNESS



Background

Rheumatoid Arthritis is a chronic multisystem disease characterized by persistent inflammatory synovitis, usually involving peripheral joints in a symmetric distribution. The potential of synovial inflammation to cause cartilage destruction and bone erosions and subsequent changes in joint integrity is the hallmark of the disease. Exact etiology is unknown. Although recent work has focused on the possible role of super antigens produced by a number of microorganism including staphylococci, streptococci and mycoplasma arthritidis. Other possible etiology mechanism in RA include a breakdown of a normal self tolerance leading to reactivity to self antigens in the joint such as type II collagen or loss of

immune regulatory control mechanism resulting in polyclonal T cell activation.

According to Ayurveda some of etiological factors such as Viruddhahara (Improper & irregular dietary habits), Viruddhachesta (Improper Physical and Psychological activities), Mandagni, Sedentary habits and exercise immediately after food are said to be responsible for origin of amavata.

Various studies on Amavata-Rheumatoid arthritis have been published in the JRAS and other scientific journals. Some of the important publications dealing with development of diseases, the Ayurvedic concepts of its etiopathogenesis, the dietetic management and effect of certain therapies are presented in this compilation on Amavata.

The Agnimandhya-GrahaniDosa has been considered to be the main factor in pathogenesis of this disease in Ayurveda. Certain studies have been conducted and reviewed to assess the gastro-intestinal function. The findings indicate impaired secretion of gastric acid secretion, deranged liver function and reduced intestinal absorption.

The cardinal features of Amavata are swelling and pain like scorpion bite over the joints like hands and legs (especially knee, ankle wrist, metacarpals and metatarsals). Based on the cardinal feature and other associated features, many effective regimens are described in Ayurvedic classics.

Owing to the gravity of the situation, a need is felt for searching the safe /effective Ayurvedic formulations to reduce the symptoms. Keeping all these view in consideration and the public health needs, the council intends to initiate scientific studies on well known and safe classical Ayurvedic formulation that is being successfully prescribed by Ayurvedic physicians without any side effects since centuries.

For the present study, coded Ayurvedic drug like RHEUMAX oil have been taken to assess its clinical safety and efficacy.

Objectives

To study the effect of Nirgudyadi oil in rheumatoid arthritis

CRITERIA FOR INCLUSION

Age between 35 - 65 years of either sex
Presence of any four of the following seven criteria (according 1987, revised criteria of American College of Rheumatology)

(a) Morning stiffness: Stiffness in and around joints lasting one hour before maximal improvement (More than 6 week's duration).

(b) Arthritis of three or more joints (at least three joint area, observed by Physician simultaneously having pain with soft tissue swelling or joint effusion, not just bony over growth) (More than 6 weeks duration).

(c) Arthritis of Hand joints (More than 6 weeks duration).

(d) Symmetric arthritis (More than 6 week's duration).

(e) Presence of Rheumatoid Nodules

(f) Serum Rheumatoid factor- positive

(g) Typical Radiographic changes of arthritis on PA view of hand & wrist radiograph that must include erosions or unequivocal bony decalcification adjacent to involve joints.

CRITERIA FOR EXCLUSION

1. Age below 35 and above 60 years.
2. Patients who develop secondary complication of RA e.g. Pleuro-pericardial disease, severely damaged joint with bed ridden patients.
3. Any other serious illness e.g. Hepatic/renal failure.
4. Patient with diagnosed other arthritis like Gouty arthritis, tuberculosis arthritis etc.
5. Patient receiving any other method of treatment.

CRITERIA FOR WITHDRAWAL

The cases with following complications will be withdrawn from the study.

1. Aggravation of the disease during the course of the trial period.
2. Discontinuation of the treatment during trial.

3. Development of any serious complications requiring change in the treatment.

2. Clinical assessment will be done and recorded on '0' day, 15th day, 30th day, 45th day.

ROUTINE EXAMINATION AND ASSESSMENT

1. The full details of history and physical examination of the patients will be recorded as per the proforma (Forms I & IA).

Joint pain

Si.	Severity of Pain	Grade	Score
1	No pain	Zero	0
2	Pain occasional, can be managed without drug	I	2
3	Pain frequent and can be managed with some pain killer	II	4
4	Pain persistent and unmanageable even with drugs	III	6

Morning stiffness

Si.		Grade	Score
1	No stiffness	Zero	0
2	Early morning stiffness upto 30 minutes	I	2
3	Early morning stiffness more than 30 minutes	II	4
4	Morning stiffness more than 45 minutes	III	6

Tenderness

Si.	Tenderness	Grade	Score
1	No tenderness	Zero	0
2	Tender but bearable	I	2
3	Tender and winced	II	4
4	Tender winced and withdraw	III	6

Swelling

Si.	Severity of Swelling	Grade	Score
1	No swelling/not making the bony land marks of joints	Zero	0
2	Just covering the bony prominences	I	2
3	Considerably above the land marks may be with positive fluctuation.	II	4
4		HI	6

RESULTS & DISCUSSION

In the present clinical study, the efficacy of Nirgudyadi Oil has been evaluated in 15 cases of Rheumatoid arthritis. Patients who presented with various symptoms of rheumatoid arthritis, were evaluated on the basis of weight gain on regular follow ups on first, 15th, 45th day of the study. After the completion of therapy. Significant changes were observed in pain, stiffness, and tenderness. This suggests that the drug has good effect on Rheumatoid arthritis.

Nirgudyadi oil was well accepted by all the patients No untoward effects were noted. The effect of Nirgudyadi oil on tenderness was remarkable. All the patients were having good relief after 4 weeks on nirgudyadi oil.

According to all Ayurvedic Prakrities significant results were seen in this pilot study.

No any adverse or unwanted observations were noted during and after the completion of 45days treatment duration.

CONCLUSION

Nirgudyadi oil was found to be effective in improvement of swelling and joint pain in rheumatoid arthritis.

No side effects were seen with drug. There was good response in terms of compliance.

Considering the excellent results of the study, it can be concluded that Nirgudyadi oil is effective in the treatment of rheumatoid arthritis, without producing any undesirable side effects. In cases of long term use and control, it may be useful if used for in same kind of doses.

A larger clinical Trial according to various Doshaprakriti for Nirgudyadi oil should be done to prove efficacy in all body types.

However, a larger clinical trial is proposed to evaluate its efficacy in a wider perspective. The present clinical trial of

Nirgudyadi oil, an Ayurvedic preparation has proved its efficacy and safety in Rheumatoid arthritis.

REFERENCES

1. Charakasamhita chakrapani teeka chaukhambha publications
2. Madhavnidanam pade shastri
3. Ashtangahridayam hemadri arunadatta teeka chaukhambha publications
4. Bhavprakash nighantu, K. C. Chunekar, Chaukhambha Publications.
5. Chopra, V.K. and Singh, K.K., Capsule (1976) : 7, 146.
 2. Graham, G.G., Am. J. Clin. Nutr. (1972) : 25, 1084.
 3. Indira Bai, K. et al., Fed. Clin. India (1973) : 1, 39.
 4. Kulsreshtha, J.K. et al., Ind. Practit. (1975) : 3, 315.
 5. Lall (Miss.) S.F. et al., Capsule (1978) : 3, 55.
 6. Chemistry of Indian Medicinal Plants, J P Dastur
 7. Nutrition Sub-committee of the Indian Academy of Pediatrics, Report of Convenor (Abstracts) (1972) : Vol. IX, No. 6.
 8. Rastogi, K.N., Probe (1978) : 3, 235.
 9. Shirole, D.B. et al., Ind. Practit. (1973) : 5, 213.
 10. Tamilarasu, S., et al., Capsule (1979)