ABSTRACT

Objective: To evaluate the therapeutic efficacy of Siddha formulation Chandamarutha Chenduram on Serum Rheumatoid factor in Uthiravatha Suronitham (Rheumatoid arthritis) patients.

Materials and methods: An open clinical trial was carried out at the OPD and IPD of National Institute of Siddha with a sample size of 21 patients of both sexes who were screened positive for Serum Rheumatoid factor before treatment. They were treated with Chandamarutha Chenduram (65 mg with palm jaggery twice a day after food) for 48 days. (48days=1 course). The trial drug Chandamarutha Chenduram was given for 7 days followed by a break (re dieting) of 5 days. The same procedure extended till the end of the course. Every first day of break (re dieting) started with head bath with the paste of Ajowan seeds and cow’s milk. Diet free of salt and tamarind was strictly followed throughout the course of treatment. The patients were screened for Serum Rheumatoid factor before and after the treatment course. There was a follow up of patients for one month without the drug administration.

Results: 5/21 patients were screened negative for Serum Rheumatoid factor after the treatment, 15/21 patients had significant reduction in Serum drug administration.

Conclusion: The drug is found to be efficacious, cost effective, easily available and simple in preparation. It can be explored for further research in the treatment of Uthiravatha Suronitham.

Keywords: Uthiravatha Suronitham, Serum rheumatoid factor, Rheumatoid arthritis.

INTRODUCTION

Siddha system of medicine is one among the ancient Indian systems of medicine which evolved and flourished in South India particularly in Tamilnadu. Siddha system recognizes the body’s innate ability to activate dormant repair mechanisms.

In Siddha system of medicine the total number of diseases are said to be 4448. Vatha diseases is a major classification of this, which are of 80 types. One among the 80 types of Vatha diseases is Uthiravatha Suronitham. It is characterised by pain and swelling in both ankle joints, knee joints and all smaller joints of the hands, feeling of tiredness, fever, loss of appetite and mental depression.

The symptomological description of the clinical entity “Uthiravatha Suronitham” is identical to those of the symptoms described under the clinical diagnosis “RHEUMATOID ARTHRITIS (RA)” in modern science.

Rheumatoid arthritis is an autoimmune disorder associated with chronic inflammatory, destructive, and deforming symmetrical poly arthritis associated with symmetrical involvement of joints.

Rheumatoid factor is an autoantibody directed against Immunoglobulin-G (IgG) and is found in the blood of 50-80% of patients with RA. Rheumatoid factor is an important prognostic marker. Those who test positive are more likely to have a worse prognosis with respect to joint destruction, physical/occupational disability, and quality of life in general.

Hence an attempt was made to investigate the changes in the Serum Rheumatoid factor with the Siddha formulation Chandamarutha chenduram which is indicated for the above said disease in the authorized Siddha test book which was proved to be safe in the preclinical studies done at NIS. It comprises of five important minerals namely Lingam (Red Sulphide of Mercury), Pooram (Hydrargrum sub chloride), Veeram (Hydrargrum per chloride), Rasachenduram (Artificial red sulphide of mercury) and Ganthagam (Sulphur).

MATERIALS AND METHODS

This work was carried out for one year at the OPD and IPD of National Institute of Siddha at Chennai. It was an open clinical trial. An approval was obtained from the Institutional Ethics Committee for conducting this trial at National Institute of Siddha. The trial drug was subjected to preclinical studies (Acute and Long term studies) at National Institute of Siddha as per WHO guidelines by the author after getting the approval from Institutional Animal Ethical Committee. Patients attending the OPD of Maruthuvam department were screened and enrolled in the study. An informed, written and signed consent was obtained before enrollment into the clinical trial. Patients with the clinical symptoms of arthritis of three or more joints, Symmetrical joint involvement, Morning stiffness, Fever, Anorexia, Positive Rheumatoid factor were examined clinically and enrolled in to the study. They were already diagnosed patients or newly diagnosed ones. The following category patients were excluded from the trial: Patients with Cardiac disease, Hypertension, Diabetes mellitus, Use of narcotic drugs, Pregnancy and nursing women, History of trauma, Tuberculosis, Bronchial Asthma and Any other serious illness. 21 patients who fulfilled the inclusion criteria were selected for the study. The drug was prepared in the Gunapadam (Pharmacology) lab of National Institute of Siddha after the authentication of the raw drugs. The raw drugs were purified and the trial drug was prepared by the author as per standard operating procedure mentioned in the protocol.

Treatment was mainly aimed at (i) Balancing the elevated humours (Vatham, Pitham and Kapam) through Siddha line of treatment (Purgation and Medication) (ii) Rejuvenating the deranged humours and udal thathukkal (physical constituents) of the patients through Siddha way of dieting, re dieting etc.

Before starting the course they were given purgation with the OP medicine Agasthier Kuzambhu 130 mg with ginger juice, early morning in empty stomach as mentioned in the literature. From the very next day the trial drug Chandamarutha Chenduram 65 mg was given with eight folds (520 mg) of palm jaggery twice the day after food for 7 days followed by a break (re dieting) of 5 days. The same procedure extended till the end of the course. Every first day of break (re dieting) started with head bath with the paste of Ajowan seeds and cow’s milk and diet free of salt, tamarind etc. Dietary advice was strictly followed during the period of drug administration as well as re dieting period.
RA dilution factor was screened before and after the treatment in the reputed laboratory by Serum/Nephelometry method with normal limit up to 15 IU/ml, in addition other lab parameters (Haematological, LFT and RFT) were also screened. The OP patients were clinically assessed once in 12 days and in case of IP patients it was done daily.

Outcome measurement was assessed by the reduction in the lab parameter- RA Factor - dilution value before and after treatment.

**Statistical Analysis**

All collected data were entered into computer using MS Excel software. The data entry was cross-checked manually. The data was analysed using SPSS version 18.0 software. The effectiveness of the drug was assessed by using paired ‘t’ test. The probability value 0.05 was taken as significant value with two sided test.

**RESULTS**

The pre clinical studies (Acute and long term toxicity studies) done as per WHO guidelines in the trial drug proved the safety of the drug for human usage. The particle size per million (PPM) of the drug subjected to analysis at Indian Institute of Technology seemed to be 2 µm which revealed the existence of the drug in micro form.

Female and male cases were 18 (85.71%) and 3 (14.29%) respectively.

1. Age and Sex distribution of patients

<table>
<thead>
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<th>Age</th>
<th>Female</th>
<th>Male</th>
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<td>20-30</td>
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<tr>
<td>2</td>
<td>30-40</td>
<td>6</td>
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</tr>
<tr>
<td></td>
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<td>3</td>
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2. Duration of illness

<table>
<thead>
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<th>No of cases</th>
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</tr>
</thead>
<tbody>
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<td>Less than 6 months</td>
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</tr>
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<td>6</td>
<td>More than 5 years</td>
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</tr>
<tr>
<td></td>
<td>Total</td>
<td>21</td>
<td>100%</td>
</tr>
</tbody>
</table>

3. RA dilution factor

Among the 21 cases, after treatment 5 (23.81%) cases were screened negative for Serum Rheumatoid factor. In 15 (71.43%) cases there was a reduction in Serum Rheumatoid factor and in 1 (4.76%) case there was a slight increase in the Serum Rheumatoid factor. Fig 1

In the present study, no adverse effects were encountered in any patient. There were no abnormalities found in the other lab parameters like LFT, RFT and haematology.

**Statistical Analysis Results:**

The mean and standard deviation was 350.4 ± 477 before treatment and 271.9 ± 435 after treatment. There was a significant reduction (P<0.05) in Serum rheumatoid factor before and after the treatment.

**DISCUSSION**

The main aim of the treatment was to study the therapeutic effect of the drug Chandramarutha Chenduram on Serum Rheumatoid factor in Uthiravatha Suronitham, the clinical features of which can be correlated to Rheumatoid arthritis in modern science.

Uthiravatha Suronitham is a Vatha disease basically in which, there occurs a derangement of Vatha humour in association with Pitta humour. Derangement of the Vatha humour leads to impairment in Udal thathakal (Physical constituents of the body) and in turn produces symptoms like prickling pain, body ache, difficulty in flexion and extension of joints, mental distress etc.

Pitta humour has the basic function of production and maintenance of the blood environment. In addition it maintains the body temperature. Hence Pitta humour when deranged produces symptoms like fever, changes in the blood environment etc.

The trial drug Chandramarutha Chenduram indicated for Vatha diseases and the adjuvant palm jaggery indicated for Pitta diseases had balanced the deranged humours. Its particle size revealed the fact of it existing in its microform (2µm) lead to the reduction in Rheumatoid factor in serum which is a prognostic marker in Rheumatoid arthritis of modern science. The pharmacological action of the trial drug can be performed in future for revealing its influence on Serum Rheumatoid factor.

**CONCLUSION**

The drug is found to be efficacious, safer, cost effective, easily available and simple in preparation. It can be explored for further research in the treatment of Uthiravatha Suronitham (Rheumatoid arthritis) and the pharmacological action of the drug particularly towards Serum Rheumatoid factor in future with a large sample size and long term follow up confirming the efficacy of the drug.

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