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Efficacy of *Toxicodendron pubescens* in relation with serum hyaluronic acid and its application on primary osteoarthritis

Dr. Ancy Abraham, Dr. ESJ Prabhu Kiran and Dr. Mini Illath Veetil

Abstract

Toxicodendron Pubescens (Rhus Tox), a Homeopathic medicine frequently used for Osteoarthritis is evaluated with the help of Serum Hyaluronic acid level. A total of 44 patients with knee Primary Osteoarthritis (OA) were taken into the study for the follow-up period up to 3 months and Serum Hyaluronic Acid is measured through Eliza test before and after administering Rhus Tox200 three time a day. Homoeopathy implies a particular way of applying drugs to diseases according to a specific Principle: known as 'Similia similibus curentur'. This implies that substances capable of causing disorder in healthy subjects are used as medicines to treat similar patterns of disorder experienced by ill people. According to aphorism 248 the dose of the same medicine may be repeated several times according to the circumstances, but only so long as until either recovery ensures, or the same remedy ceases to do good and the rest of the disease presenting a different group of symptoms demands a different homoeopathic remedy. Analyzed the symptoms according to the Knee injury and Osteoarthritis Outcome Score (KOOS), which was developed as an extension of the WOMAC Osteoarthritis Index with the purpose of evaluating short-term and long-term symptoms and function in subjects with knee injury and osteoarthritis. The KOOS holds five separately scored subscales: Pain, other Symptoms, Function in daily living (ADL), Function in Sport and Recreation (Sport/Rec), and knee-related Quality of Life (QOL). A significant alteration in Serum Hyaluronic Acid is noted in patients suffering from Primary Osteoarthritis is marked with significant P value.

Keywords: Osteoarthritis, toxicodendron pubescens, rhus tox, hyaluronic acid, homoeopathy

1. Introduction

Osteoarthritis (OA) is a slow, progressive, degenerative joint diseases affecting the articular cartilage of the joints and ultimately leading to disability. Commonly it affect the Knee joint^[1]. Pain is a major complaint compelling patient to seek medical advice. Incidence of the joint being disabled is consistent with the period of individual's suffering. Primary Osteoarthritis occurs in joints without any previous pathology or any predisposing cause^[2]. Higher levels of Hyaluronic acid (HA) in synovial fluid in comparison with serum were reported in patients with Osteoarthritis, suggesting its local production. Serum Hyaluronic Acid levels were shown to be elevated in patients with Osteoarthritis and demonstrated as a possible predictive factor for further development of Osteoarthritis of the knees and hips^[3]. The Homoeopathic remedy Rhus Tox is prepared from poison ivy, a creeping shrub that is found growing naturally all over North America. Rhus Tox affects fibrous tissue markedly-joints, tendons, sheaths-aponeurosis, etc, producing pains and stiffness. Worse, cold, damp weather, at night. Numbness and formication, after overwork and exposure.

1.1 Rhustox

Rhus Tox (*Toxicodendron pubescens*) is found in sandy woods in the eastern United States^[4]. The tincture contains Rhoitannic acid (C₁₈H₂₈O₁₃) and Toxicodendric acid, a poisonous, volatile principle^[5]. A peculiarity of the plant is that it is more poisonous during the night, and when bursting in to leaves, or at any time in June or July when the sun is not shining upon it. Those who Care for Signatures will not fail to connect the cardinal aggravations of RhusTox- at night and from damp - with the increased the virulence of the plant at night and in damp atmosphere^[6].

Main indication of Rhustox is

- Rhus affects fibrous tissues markedly-joints, tendon, sheaths- aponeurosis etc., producing pains and stiffness of muscles and joints. Rheumatism in cold damp season

[7].

- The first and the foremost feature of Rhustox is amelioration of all symptoms from continual motion
- The second characteristic feature is the great sensitiveness to open air and to all atmospheric changes [8].
- Tearing asunder pains. Parts feels sore bruised and stiff
- Pains are tearing, shooting, stitching, worse at night, cannot rest in any position
- Tenderness about the knee joint.
- Hot painful swelling of joints
- Soreness of condyles of bones.
- The Greatest rigidity and pain is experienced on first moving the joints after rest, and on waking up in the morning. After the joints are moved for a while the pain is lessened [9].

Hyaluronan (HA) was formerly called Hyaluronic acid or Hyaluronate. It is found in all extra cellular matrixes and in most tissues, its molecules being relatively enormous: Hyaluronic acid forms very viscous solution which are probably the major lubricants in Synovial joints [10].

1.2 Functions of hyaluronic acid in joints

- Articular cartilage.
- Hyaluronic acid (HA) is crucial for the structural and functional integrity of articular cartilage and responsible for unique viscoelastic properties of the synovial fluid. The very large aggregates (>108kDa) that are thus formed may be the essential compression – resisting units in cartilage.
- Hyaluronic acid is the most active form of Glycosaminoglycans (GAG's)
- The molecular mass of Hyaluron in cartilage is not
- Constant and decreases considerably during maturation

and aging of tissue [11].

1.3 Synovial fluid

- It works as a shock absorber.
- Lubricating the fluid in the joint tissues, as well as stabilizing its breakdown.
- It removes the waste products, often acidic in nature, that arise from the destruction of the cartilage matrix and hence eases joint pain.
- As an antioxidant, it further supports joint health by protecting joint destruction due to free radicals [12].

1.4 Fibrous capsule [13]

Anti-inflammatory and anti-edematous properties. The molecular weight (size) of Hyaluron in cartilage decreases with age, but the amount increases. It results in increasing the viscosity of synovial fluid and leads to stiffness, loss of flexibility, destruction of articular cartilage, inflammation of fibrous capsule, and edema result in primary Osteoarthritis [14].

1.5. The fundamental idea of homoeopathy

Homoeopathy implies a particular way of applying drugs to diseases according to a specific Principle: known as ‘Similia similibus curentur’ (‘Let like be treated by likes’) [15], stated by the German physician Samuel Hahnemann (1755–1843) in 1796. This implies that substances capable of causing disorder in healthy subjects are used as medicines to treat similar patterns of disorder experienced by ill people.

In this study the symptoms of Rhustox during drug proving have many similarities with action of Hyaluronic acid in joints like knee.

1.6 The similarity of hyaluronic acid and Rhustox [16]

Table 1: Table show Rhustox

S. no.	Symptoms common to Osteo arthritis and Rhustox	Role of Hyaluron in Osteoarthritis and the similarities of Hyaluron and Rhustox
1	<ul style="list-style-type: none"> ▪ Sphere of action- synovial joints and the related structure ▪ Adapted to person of rheumatic diathesis 	<ul style="list-style-type: none"> ▪ One of the important content of synovial fluid who nourishes the joints and protect from wear and tear prevents osteoarthritis
2	<ul style="list-style-type: none"> ▪ Absence of sunlight together with dampness seems to favor the exhalation of toxicodendron acid. ▪ When the sky becomes cloudy he put on a warm garment as an act of precaution 	<ul style="list-style-type: none"> • Cold damp weather the content of Hyaluronic acid increases in synovial fluid leads to increases in viscosity
3	<ul style="list-style-type: none"> ▪ Symptoms of Rhustox 1. stiffness (with in 4hrs of drug proving) ▪ < from first movement pain ▪ > continuous movement ▪ < cold damp weather ▪ < cold air ▪ < morning 	<ul style="list-style-type: none"> ▪ When viscosity of synovial fluid increase ▪ More movements of joint encourage more lubrication ▪ Sometimes a person experiences difficulty in starting
	<ul style="list-style-type: none"> ▪ movements during morning hours but when movements are continued, stiffness of joints lessens 	
	<ul style="list-style-type: none"> • Pains are tearing, shooting, stitching, worse at night, cannot rest in any position • Soreness of condyles of bones. Tenderness about the knee joint. • Hot painful swelling of joints • As if bones were scraped with knife (the cartilage that cushions your joints starts to wear down, causing the bones to rub together. The bone-on-bone action leads to inflammation of the joints). 	<ul style="list-style-type: none"> ▪ It works as a shock absorber lubricating the fluid in the joint tissues as well as stabilizing its breakdown.
	<ul style="list-style-type: none"> ▪ Anti-inflammatory and anti-edematous properties. Works as an antioxidant and free radical scavenger, maintains cushions joints has an antibacterial 	
	<ul style="list-style-type: none"> ▪ Improve and increase the mental alertness 	
5	<ul style="list-style-type: none"> ▪ Great restlessness anxiety apprehension cannot remain in bed must change in position often to obtain relief from pain 	

1.7 How do Homoeopathic medicines acts

Homoeopathic medicines are aimed to direct and stimulate the body's self-regulatory mechanisms.

1.8 Selection of potency

There are five-fold considerations for choosing the potency of Homoeopathic Drug

- 1 The Susceptibility of the patient,
 1. The seat of disease,
 2. The nature and intensity of the disease,
 3. The stage and duration of the disease,
 4. The previous treatment of the disease,

Repetition of homoeopathic remedy

According to aphorism 248 the dose of the same medicine may be repeated several times according to the circumstances, but only so long as until either recovery ensures, or the same remedy ceases to do good and the rest of the disease presenting a different group of symptoms demands a different homoeopathic remedy^[17]

It is purely depended on patient.

There was a Research Article shows that Hyaluronic acid levels may have predictive value for the progression of knee osteoarthritis^[18]. Hyaluronic acid levels have predictive value for the progression of knee Osteoarthritis. In this Research it is evaluated that the "Efficacy of Toxicodendron Pubescens in relation with Hyaluronic Acid and its application in Primary osteoarthritis." The parameters used in this study is the Clinical evaluation of the symptoms according to the KOOS Scale as well as Serum Hyaluronic acid level. Serum Hyaluronic acid is measured before and after the treatment.

2 Methodology

2.1 Sample details

Patients attending the OPD of Father Muller Homoeopathic Hospital Deralakatte were enrolled for study. A total number of 70 Patients between the age group 40 to 70 were screened to ensure enrollment of 44 patients in the trial. The Diagnosis was made on basis of clinical presentation. Detailed case study was done and patients were analyzed using KOOS Scale, before and after the treatment. To get the accurate Serum Hyaluronic acid level the blood has withdrawn on appropriate time before the medicine and after the medicine when the symptoms were better according to the KOOS Scale Score.

2.2 Inclusion criteria

Age 40 to 70, Both sexes are included, Patients selected on the basis of clinical presentation, history and examination with serum hyaluronic acid level, Only primary

osteoarthritis cases considered, Only those patients are considered whose complaint indicated for Rhus Tox and change in serum hyaluronic acid.

2.3 Exclusion criteria

Cases other than primary osteoarthritis is not considered. Those Patients are not considered, whose symptoms not indicated for Rhus Tox and change in serum hyaluronic acid.

2.4 Materials and Method

Approval of the Institutional Ethics Committee of Father Muller Charitable Institution was obtained before the initiation of the project and the procedures followed were in accordance with the ethical guidelines for biomedical research provided by the Indian Council of Medical Research, New Delhi. Informed consent was obtained from each individual before the screening study.

2.5 Source of data

Patients attending the OPD of Father Muller Homoeopathic Hospital Deralakatte were enrolled for study. A total number of 70 Patients between the age group 40 to 70 were screened to ensure enrollment of 44 patients in the trial. The Diagnosis was made on basis of clinical presentation. Detailed case study was done and patients were analyzed using KOOS Scale, before and after the treatment. To get the accurate Serum Hyaluronic acid level the blood has withdrawn on appropriate time before the medicine and after the medicine when the symptoms were better according to the KOOS Scale Score. Purposive sampling, after the collection of blood samples for pretest Rhus Tox 200 is administered according to the protocol.

2.6 Research methodology

Criteria for deciding the efficacy of Rhus Tox in Primary Osteoarthritis is based on the intensity of symptoms, change in KOOS Criteria and Changes in Serum Hyaluronic acid level. Data from the sample were subjected to paired t test because KOOS criteria is only to see the follow up improvement and second withdrawal of blood to determine the significance of the efficacy of the drug.

2.7 Assessment of effectiveness

The data of 44 patients were statistically analyzed. According to Statistical analysis the effectiveness of Rhus Tox in Primary Osteoarthritis with change in Serum Hyaluronic acid is Highly Significant. There was Statistically High Significant drop in Serum Hyaluronic acid level after the treatment.

Table 1: Serum hyaluronic acid value in elisa machine

Workspace/Method/Sample IDFather Mulier Medical College Hospital Microbiology.yaluronan Assay 16-12-16.smp
Date: 2016-12-16

Username Administrator

1 Sample ID 1
2 Layout
3 Difference data

1	2	3
A1	ST1_1	1.6237
B1	ST1_2	0.8883
C1	ST1_3	0.4893
D1	ST1_4	0.3278
E1	ST1_5	0.1765
F1	ST1_6	0.1096
G1	SM1_1	0.3767
H1	SM1_2	0.1874
A2	SM1_3	0.7264
C2	SM1_5	1.3096
E2	SM1_7	0.525
G2	SM1_9	0.3177

QC Validation criteria

NoCalc

Time: 15:59:01 Bio-Rad PR4100 Page:1/1

Table 1.2: Serum hyaluronic acid value in elisa machine

Workspace/Method/Sample IDFather Mulier Medical College Hospital Microbiology.URONIC ACID 21-11-16.smp
Date: 2016-12-21

Username Administrator

1 Sample ID 1
2 Layout
3 Difference data

1	2	3
A1	ST1_1	0.1104
B1	ST1_2	0.1863
C1	ST1_3	0.3645
D1	ST1_4	0.7401
E1	ST1_5	1.6471
F1	ST1_6	2.0149
G1	SM1_1	1.7101
H1	SM1_2	2.5352
A2	SM1_3	2.3473
B2	SM1_4	1.6929
C2	SM1_5	1.1716
D2	SM1_6	0.855
E2	SM1_7	1.1096
F2	SM1_8	1.1081
G2	SM1_9	0.4816
H2	SM1_10	2.6678
A3	SM1_11	NoCalc
B3	SM1_12	NoCalc
C3	SM1_13	1.8901
D3	SM1_14	NoCalc
E3	SM1_15	3.2006
F3	SM1_16	NoCalc
G3	SM1_17	2.1771
H3	SM1_18	1.6203
A4	SM1_19	NoCalc
B4	SM1_20	2.7862
C4	SM1_21	0.5529
D4	SM1_22	2.8094
E4	SM1_23	0.7067
F4	SM1_24	1.2745
G4	SM1_25	1.6265
H4	SM1_26	2.8978
A5	SM1_27	1.0978
B5	SM1_28	3.2233
C5	SM1_29	NoCalc
D5	SM1_30	3.4133
E5	SM1_31	2.3934
F5	SM1_32	3.2396
G5	SM1_33	1.3336
H5	SM1_34	2.7615
A6	SM1_35	1.7151
B6	SM1_36	1.6969
C6	SM1_37	3.7502
D6	SM1_38	1.415

Time: 15:18:50 Bio-Rad PR4100 Page:1/2

Table 1.3: Serum hyaluronic acid value in elisa machine

Workspace/Method/Sample IDFather Mulier Medical College Hospital Microbiology.URONIC ACID 21-11-16.smp
Date: 2016-12-21

1 Sample ID 1
2 Layout
3 Difference data

1	2	3
E6	SM1_39	3.8747
F6	SM1_40	1.2174
G6	SM1_41	2.9575
H6	SM1_42	3.0058
A7	SM1_43	3.5767
B7	SM1_44	1.3149
C7	SM1_45	2.1189
D7	SM1_46	2.3322
E7	SM1_47	1.2077
F7	SM1_48	3.4611
G7	SM1_49	1.0962
H7	SM1_50	1.5379
A8	SM1_51	3.0632
B8	SM1_52	1.2217
C8	SM1_53	1.8189
D8	SM1_54	2.4574
E8	SM1_55	2.0844
F8	SM1_56	1.918
G8	SM1_57	2.8165
H8	SM1_58	NoCalc

QC Validation criteria
NoCalc

Time: 15:18:50 Bio-Rad PR4100 Page 2/2

Table 1.4: Serum hyaluronic acid value in elisa machine

Workspace/Method/Sample IDFather Mulier Medical College Hospital Microbiology.ORNIC ACID 18-5-2017.smp
Date: 2017-05-18
Username Administrator

1 Sample ID 1
2 Layout
3 Difference data

1	2	3
A1	ST1_1	0.067
B1	ST1_2	0.1141
C1	ST1_3	0.2411
D1	ST1_4	0.4074
E1	ST1_5	0.5893
F1	ST1_6	1.4847
G1	SM1_1	1.6974
H1	SM1_2	1.2506
A2	SM1_3	2.0172
B2	SM1_4	1.7136
C2	SM1_5	2.6869
D2	SM1_6	1.5809
E2	SM1_7	1.1815
F2	SM1_8	0.4094
G2	SM1_9	0.7485
H2	SM1_10	NoCalc
A3	SM1_11	0.9314
B3	SM1_12	3.8867
C3	SM1_13	1.2774
D3	SM1_14	0.7608
E3	SM1_15	0.3488
F3	SM1_16	0.4692
G3	SM1_17	1.8788
H3	SM1_18	0.7159
A4	SM1_19	0.7872
B4	SM1_20	0.8462
C4	SM1_21	0.8562
D4	SM1_22	0.0813
E4	SM1_23	0.4341
F4	SM1_24	0.2536
G4	SM1_25	0.1073
H4	SM1_26	0.1211
A5	SM1_27	0.4423
B5	SM1_28	0.6096
C5	SM1_29	0.356
D5	SM1_30	1.5254
E5	SM1_31	0.1818
F5	SM1_32	2.0256
G5	SM1_33	1.8054
H5	SM1_34	3.1489
A6	SM1_35	0.6106
B6	SM1_36	0.8092
C6	SM1_37	1.353
D6	SM1_38	0.4988

Time: 16:18:28 Bio-Rad PR4100 Page 1/2

Table 1.5: Serum hyaluronic acid value in elisa machine

Workspace/Method/Sample ID\Father Mulier Medical College Hospital Microbiology.ORNIC ACID 18-5-2017.smp
Date: 2017-05-18

1 Sample ID 1
2 Layout
3 Difference data

1	2	3
E6	SM1_39	0.5612
F6	SM1_40	0.0732
G6	SM1_41	0.6493
H6	SM1_42	0.6038
A7	SM1_43	1.0658
B7	SM1_44	1.002
C7	SM1_45	0.0827
D7	SM1_46	0.7427
E7	SM1_47	0.4224
F7	SM1_48	1.2682
G7	SM1_49	1.3821
H7	SM1_50	0.6209

QC Validation criteria
NoCalc

Time: 16:18:28 Bio-Rad PR4100 Page 2/2

Table 1.6: Serum hyaluronic acid value in elisa machine

Workspace/Method/Samp\Father Mulier Medical College Hospital Microbiology HYLUN 19-05-2017.smp
Date: 2017-05-19

Username Administrator
1 Sample ID 1
2 Layout
3 Difference data

1	2	3
A1	ST1_1	0.0626
B1	ST1_2	0.0965
C1	ST1_3	0.1441
D1	ST1_4	0.2569
E1	ST1_5	0.5026
F1	ST1_6	0.8267
G1	SM1_1	0.5064
H1	SM1_2	1.8707
A2	SM1_3	0.7291
B2	SM1_4	0.6158
C2	SM1_5	2.3342
D2	SM1_6	0.4191
E2	SM1_7	0.8207
F2	SM1_8	0.7528
G2	SM1_9	0.3378
H2	SM1_10	0.3414
A3	SM1_11	0.2271
B3	SM1_12	0.0858
C3	SM1_13	2.4346
D3	SM1_14	0.1041
E3	SM1_15	0.9206
F3	SM1_16	0.6677
G3	SM1_17	0.4103
H3	SM1_18	0.4717
A4	SM1_19	0.3556
B4	SM1_20	0.7083
C4	SM1_21	0.5338
D4	SM1_22	0.6903
E4	SM1_23	0.4957
F4	SM1_24	0.3493
G4	SM1_25	0.9517
H4	SM1_26	0.2633
A5	SM1_27	0.2689
B5	SM1_28	0.3612
C5	SM1_29	2.1998
D5	SM1_30	0.8133
E5	SM1_31	0.7049
F5	SM1_32	1.0787
G5	SM1_33	3.6619
H5	SM1_34	0.7626
A6	SM1_35	1.4647

QC Validation criteria

Time: 14:57:59 Bio-Rad PR4100 Page 1/2

2.8 Plan of data analysis

The effectiveness of Rhus Tox in Primary Osteoarthritis with changes in Serum Hyaluronic acid before and after the treatment is shown in table 2 with Mean value before

treatment as 64.88, after treatment 33.82 and a Standard Deviation of difference 24.57, the “t” value is 8.386 and $p < 0.001$ and Highly Significant.

Table 1: Effectiveness and Significant P Value

	N	Mean	Std. Deviation	Mean difference	S.D of difference	Mean change (%)	t value	p
Before	44	64.88	18.61	31.06	24.57	47.88	8.386	.000
After	44	33.82	22.75					<0.001, HS

Table 2: Standard Deviation

Before	Mean Std. Deviation	
	64.88	18.61
After	33.82	22.75

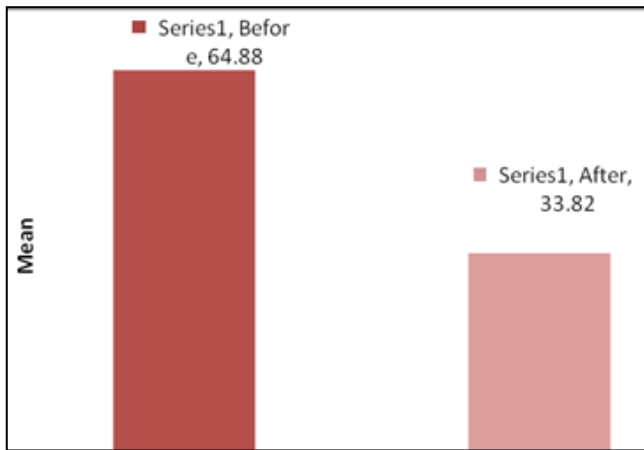


Fig 1: Significant drop in serum hyaluronic acid level after the administering Rhus Tox

Table 3: Improvement of osteoarthritis symptoms in percentage

N	Minimum	Maximum	Mean	Std. Deviation
44	50	90	65.45	12.474

Table 4: Improvement of osteoarthritis symptoms in percentage

Percent		
50	50	25
60	60	27.3
70	70	22.7
80	80	18.2
90	90	6.8
Total	Total	100

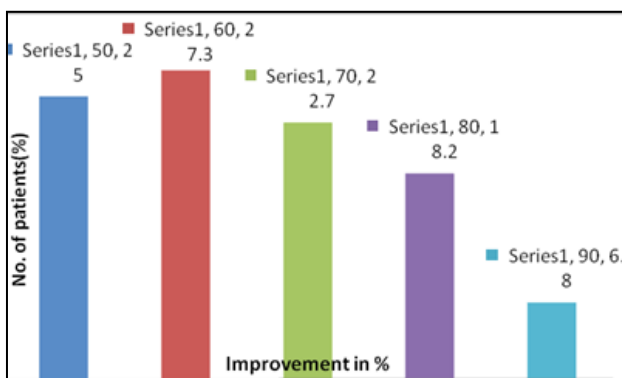


Fig 2: Improvement of osteoarthritis symptoms according to the percentage

Table 5: Improvement of Osteoarthritis Symptoms according to Age

Age Group	Frequency	Percent
40 - 50	10	22.7
51 - 60	24	54.5
61 - 70	10	22.7
Total	44	100.0

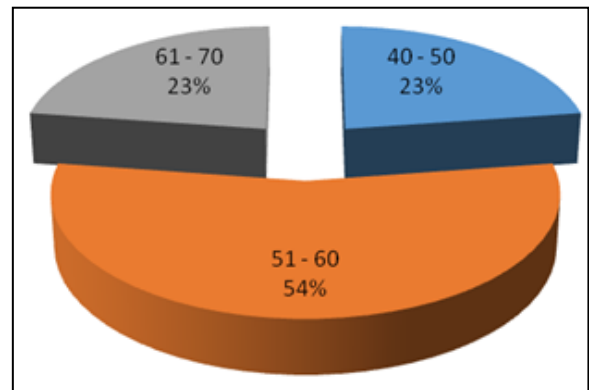


Fig 3: Improvement of osteoarthritis symptoms according to age

Conclusion

The objective of the study was mainly to evaluate the role of Rhus Tox in Primary Osteoarthritis. A group of patients suffering from primary knee Osteoarthritis were selected for the study. Blood samples were taken before and after treatment according to Koos Scale. Out of 70 cases 44 cases have taken for statistical analysis according to sample size of the research. Elisa was done for detecting the level of Serum Hyaluronic acid under the supervision of Microbiology and test was done by Lab Technician. Value was evaluated by Biochemist from Father Muller Medical College. Data has taken for Statistical analysis to a statistician. The Statistical analysis of the data proves that the drug Rhus Tox is effective in Primary Osteoarthritis. Rhus Tox is acting in Primary Osteoarthritis by making changes in Serum Hyaluronic acid level. Serum Hyaluronic acid is the one of the prognostic criteria for Osteoarthritis. The drop in Mean value of Serum Hyaluronic acid from 64.88n/ml to 33.82ng/ml. It is observed that all 44 patients who were suffering from Primary Osteoarthritis showed the improvement after giving Rhus Tox 200 and also could see there is significant change in the Serum Hyaluronic acid level. Age group was 40 to 70, and Rhus Tox is given from one to twelve weeks according to the clinical presentation. The Effectiveness of Rhus Tox for changing the Serum Hyaluronic acid is statistically analyzed. The mean value change in percentage is 47.88 and the t value is 8.386 with a p value <0.001, Highly Significant. In this study it is clear

that irrespective of age and duration of treatment there is High significance in change in Serum Hyaluronic acid with the administration of Rhus Tox in Primary Osteoarthritis case.

Toxicodendron Pubescens (Rhus Tox) is effective for Primary Osteoarthritis by altering Serum Hyaluronic acid level. On the basis of fundamental principle of Homoeopathy 'Similia similibus curentur' the study explains scientifically, that Toxicodendron Pubescens (Rhus Tox) is effective in primary osteoarthritis by correcting Serum Hyaluronic acid level. Its action results in altering the composition of the Hyaluronic acid similar to the changes that occur in Primary Osteoarthritis.

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Ethical approval

Approval of Institutional Ethics Committee of Father Muller Charitable Institution was obtained before the initiation of the project, and the procedures followed were in accordance with the ethical standards provided by Indian Council of Medical research, New Delhi. Informed consent was obtained from each individual before the screening study. The clinical trial is registered in the Clinicaltrial.gov protocol registration system (CTRI/2015/11/006350 [Registered on: 09/11/2015]).

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Ref. No	FMMC/FMIEC/2363/2015	Date : 23.07.2015
Protocol title: "EFFICACY OF TOXICODENDRON PUBESCENS IN RELATION WITH HYALURONIC ACID AND ITS APPLICATION ON PRIMARY OSTEOARTHRITIS"		
Principal Investigator: : Dr. Ancy Abraham		
Name & Address of Institution : Dr. Ancy Abraham Lecturer, Dept. of Anatomy, FMHMC, Deralakatte, Mangalore - 575018.		
New review	Revised review ✓	Expedited review
Date of review: 22/07/2015		
Date of previous review, if revised application: 11/07/2015		
Decision of the Ethics Committee:		
> Recommended ✓		
> Recommended with suggestions		
> Revision/ Resubmission		
> Rejected		
Suggestions /Reasons/Remarks: Nil		
Recommended for a period of : 1 Year		

Fig 4: Approval of institutional ethics committee

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