

**UNIVERSITY OF JAMMU
JAMMU & KASHMIR**



COMPLETE PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

SYNOPSIS BY

DR. BEENISH RAFIQ

FOR THE DEGREE OF AYURVEDA VACHASPATI

M.D. (AYURVEDA) IN KAYACHIKITSA

DEPARTMENT OF PG STUDIES IN KAYACHIKITSA,

JAMMU INSTITUTE OF AYURVEDA AND RESEARCH, JAMMU – 181123

TITLE OF THE SYNOPSIS

**“A COMPARATIVE CLINICAL STUDY OF *ERANDA BEEJA PAYASA* AND
RASANADI GUGGUL IN THE MANAGEMENT OF *GRIDHRASI* WITH
SPECIAL REFERENCE TO SCIATICA”**

GUIDED BY

DR. SOURABH GUPTA M.D. (AYU.)

ASSOCIATE PROFESSOR

DEPARTMENT OF PG STUDIES IN KAYACHIKITSA

JAMMU INSTITUTE OF AYURVEDA AND RESEARCH, JAMMU-181123

CO-GUIDED BY

DR. RADHIKA GUPTA M.D. (AYU.)

ASSISTANT PROFESSOR

DEPARTMENT OF PG STUDIES IN KAYACHIKITSA

JAMMU INSTITUTE OF AYURVEDA AND RESEARCH, JAMMU-181123

NAME OF THE INSTITUTE

JAMMU INSTITUTE OF AYURVEDA AND RESEARCH, JAMMU 181123

**JAMMU INSTITUTE OF AYURVEDA AND RESEARCH,
JAMMU – 181123**



CERTIFICATE OF SUPERVISION

This is to certify that we will supervise the thesis/research work of **DR. BEENISH RAFIQ** 1st Year M.D. student, the synopsis of which titled as “**A COMPARATIVE CLINICAL STUDY OF ERANDA BEEJA PAYASA AND RASANADI GUGGUL IN THE MANAGEMENT OF GRIDHRASI WITH SPECIAL REFERENCE TO SCIATICA**” is enclosed here with, for the research work to be done during the second and third year of M.D *Kayachiktisa*. The Synopsis submitted is selected and prepared under our guidance.

GUIDED BY:-

**DR. SOURABH GUPTA
M.D. (AYU.)
ASSOCIATE PROFESSOR
DEPARTMENT OF PG STUDIES
IN KAYACHIKITSA
JAMMU INSTITUTE OF
AYURVEDA AND RESEARCH,
JAMMU-181123**

CO-GUIDED BY:-

**DR. RADHIKA GUPTA
M.D. (AYU.)
ASSISTANT PROFESSOR
DEPARTMENT OF PG STUDIES
IN KAYACHIKITSA
JAMMU INSTITUTE OF
AYURVEDA AND RESEARCH,
JAMMU-181123**

**JAMMU INSTITUTE OF AYURVEDA AND RESEARCH,
JAMMU – 181123**



ENDORSEMENT BY THE H.O.D.

Certified that adequate facilities for working on the subject “**A COMPARATIVE CLINICAL STUDY OF *ERANDA BEEJA PAYASA* AND *RASANADI GUGGUL* IN THE MANAGEMENT OF *GRIDHRASI* WITH SPECIAL REFERENCE TO SCIATICA**” exist in the Department and will be provided to the candidate for the study.

**PROF. (DR.) NITIN MAHAJAN
M.D. (AYU.)
PROFESSOR & H.O.D.
DEPARTMENT OF PG STUDIES
IN KAYACHIKITSA
JAMMU INSTITUTE OF AYURVEDA
AND RESEARCH, JAMMU-181123**

**JAMMU INSTITUTE OF AYURVEDA AND RESEARCH,
JAMMU – 181123**



CERTIFICATE BY VICE PRINCIPAL

Certified that adequate facilities for working on the subject “**A COMPARATIVE CLINICAL STUDY OF *ERANDA BEEJA PAYASA* AND *RASANADI GUGGUL* IN THE MANAGEMENT OF *GRIDHRASI* WITH SPECIAL REFERENCE TO SCIATICA**” exist in the Department, College and Hospital and will be provided to the candidate for the study.

VICE PRINCIPAL

**PROF. (DR.) MANU SHARMA
M.D. (AYU.)
JAMMU INSTITUTE OF AYURVEDA
AND RESEARCH, JAMMU-181123**

**JAMMU INSTITUTE OF AYURVEDA AND RESEARCH,
JAMMU – 181123**



CERTIFICATE BY DIRECTOR (ACADEMICS)

Certified that adequate facilities for working on the subject “**A COMPARATIVE CLINICAL STUDY OF *ERANDA BEEJA PAYASA* AND *RASANADI GUGGUL* IN THE MANAGEMENT OF *GRIDHRASI* WITH SPECIAL REFERENCE TO SCIATICA**” exist in the Department, College and Hospital and will be provided to the candidate for the study.

DIRECTOR (ACADEMICS)

**PROF. (DR.) VIKAS GUPTA
M.D. (AYU.)
JAMMU INSTITUTE OF AYURVEDA
AND RESEARCH, JAMMU-181123**

**JAMMU INSTITUTE OF AYURVEDA AND RESEARCH,
JAMMU – 181123**



CERTIFICATE BY PRINCIPAL

Certified that adequate facilities for working on the subject “**A COMPARATIVE CLINICAL STUDY OF *ERANDA BEEJA PAYASA* AND *RASANADI GUGGUL* IN THE MANAGEMENT OF *GRIDHRASI* WITH SPECIAL REFERENCE TO SCIATICA**” exist in the Department, College and Hospital and will be provided to the candidate for the study.

PRINCIPAL

**PROF. (DR.) NITIN MAHAJAN
M.D. (AYU.)
JAMMU INSTITUTE OF AYURVEDA
AND RESEARCH, JAMMU-181123**

BIO-DATA

NAME OF THE SCHOLAR	DR.BEENISH RAFIQ
FATHER'S NAME	MR.MOHD RAFIQ CHASHTI
MOTHER'S NAME	MRS. QUMMER KULSOOM
PERMANENT ADDRESS	WARD NO 10 JANYAR, CHANDAK TEHSIL HAVELI DISTT POONCH 185101
PREVIOUS EXAM PASSED	B.A.M.S
NAME OF THE DEPARTMENT	DEPARTMENT OF PG STUDIES IN KAYACHIKITSA
NAME OF THE INSTITUTE	JAMMU INSTITUTE OF AYURVEDA AND RESEARCH, JAMMU – 181123
LANGUAGE OF DISSERTATION	ENGLISH, SANSKRIT
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ENROLLMENT NO.	

DATED :-

SIGNATURE OF SCHOLAR

INTRODUCTION:

Ayurveda is the first and foremost spiritual science that offers a scientific approach to live in harmony with nature. Ayurveda is the most ancient healing science and ideal approach for an appropriate life style. According to this science, proper choice of *Ahara and Vihara* helps to achieve healthy life by maintaining or restoring equilibrium of the body and mind.

“स्फिक्पूर्वा कटिपृष्ठोरुजानुजङ्घापदं क्रमात् | गृध्रसी स्तम्भरुक्तोदैर्गृह्णाति स्पन्दते मुहुः||” [च.चि 28/56]

Gridhrasi is a *Vata Vyadhi* characterized by *Stambha* (stiffness), *Toda* (pricking pain), *Ruk* (pain) and *Spandana* (frequents tingling). These above mentioned Lakshana's initially affect *Sphik* (buttock) as well as posterior aspect of *Kati* (waist) and then gradually radiates to posterior aspects of *Uru* (thigh), *Janu* (knee), *Jangha* (calf) and *Pada* (foot).¹ Signs and symptoms of *Gridhrasi* are similar to Sciatica. Sciatica is a disease having symptoms such as pain, numbness, tingling and weakness starting from the lowerback and or buttocks and radiating towards the foot through the back of the thigh, knee joint and leg when one or more of the nerve roots forming the sciatic nerve or the sciatic nerve alone is either compressed or irritated.

The modern treatment of sciatica is not satisfactory and includes use of analgesics and few surgical procedures which is often associated with many adverse effects. Because of such problems, it effects not only the social and economic position of the individual and his family, it also leads to draining of national resource due to work hours lost, resulting into diminished production.

In India, low back pain is among the most prevalent complaints, affecting 70% to 80% of the population. The most typical intervertebral disc prolapses among the numerous causes of low back pain. L4-L5 and L5-S1 discs are most frequently impacted in 95% of lumbar disc herniations, and the pain may be limited to the lower back exclusively or described as affecting the leg, buttock, or hip, which frequently describes the characteristics of Sciatica syndrome.

NEED FOR STUDY

The life time incidence of Sciatica varies from 10-40% while the annual incidence of an episode of Sciatica can be between 1% to 5% [2]. It is most common among people in 40s and 50s. Low back pain has been cited as fifth most common cause for hospitalization. [3]

There are many limitations for wide acceptance of surgical treatment presently available for this ailment in contemporary science. Ayurveda offers us good treatment protocol to manage such entity. By taking into consideration more prevalence rate, there is a great need to find an effective remedy.

In some cases if nerve compression is more; surgical procedures like laminectomy, discectomy are indicated but these surgical procedures are expensive with their limitations. In Ayurveda, various methods used in the treatment of *Gridhrasi* are; *Bheshaja*, *Snehana*, *Swedana*, *Siravedha*, *Agnikarma* and *Basti*.

Hence this study is an effort to highlight the efficacy of *Ayurvedic* treatment in Sciatica. *Shamana Ausadhi* is mentioned in our classical text for the management of *Gridhrasi*⁴. The present *Eranda beeja payas* which is mentioned in *Bhaishajya Ratnavali*⁵ used as *Shamana Ausadhi*, is taken to assess its efficacy on *Gridhrasi* w.s.r to Sciatica.

पिष्टैरण्डफलं क्षीरे सविश्वं वा फलं रुबोः ।
पायसो भक्षितः सिद्धो गृध्रसीकटिशूलनुत्॥ [भै.र.चि.26 /42]

PREVIOUS WORK DONE

❖ WORK DONE ON DISEASE:

In 2021 Ayurved Ruganallya And Sterling Multispeciality Hospital Nigdi Pradhikaran Pune, Maharashtra - To Compare The Effectiveness Of *Krushna Churna* And *Parijatak Gugulu* In The Treatment Of *Gridhrasi* (Sciatica).

In 2020 P D Patel Ayurveda Hospital, Gujarat - A Comparative Study Of *Troyodasangaguggulu* And *Rasnadigutika* In The Management Of *Gridhrasi* (Sciatica).

In 2019 S.D.M. Hassan College Of Ayurveda, Udupi 2019: A Comparative Clinical Study On The Effect Of *Nirgundi Taila* And *Nirgundi Kashayam Kati Basti* In *Gridhrasi*

In 2018 *Kayachikitsa* Department, Dr. D.Y. Patil College Of Ayurved And Research Centre, Pimpri, Pune Maharashtra- A Comparative Clinical Study On The Effect Of *Rasna Kashaya* & *Erandamool Kashaya* In *Gridhrasi*

In 2014 Jammu Institute Of Ayurveda And Research ;Clinical Evaluation Of *Maha Nimba Mula Twak Ghana Vati* In The Management Of *Ghridhrasi* W.S.R To Sciatica In The Year 2014-2015 By Dr. Rinki Langeh.

In 2013 Jammu Institute Of Ayurveda And Research ;A Comparative Study Of *Rasnadi Guggul* And *Kati Basti* In The Pain Management Of *Ghridhrasi* W.S.R To Sciatica. In The Year 2013-2014 By Dr. Poonam Gupta

❖ WORK DONE ON DRUG:

In 2021 Department Of *Kayachikitsa* , Ayurvedic And Unani Tibbia College And Hospital ,Delhi - A Comparative Study On The Effect Of *Eranda Kshar Yoga* And *Tryushnadi Guggulu* In The Management Of *Medoroga* W.S.R. To Dyslipidemia In The Year 2021

In 2021 Sumatibhai Shaha Ayurved College And Hospital Hadapsar Pune Maharashtra - A Comparative Clinical Study Of *Erandamula Siddha Ksheera Basti* And *Tila Taila Janubasti* With *Erandamula Siddha Ksheera Basti* In *Janu Sandhigata Vata*. In The Year 2021

In 2020 Parul Ayurved Hospital *Shalya Tantra* Department Opd No.116 P.O. Limda Parul University Vadodara Gujarat A Clinical Study To Evaluate The Effect Of *Erandadi Churna* In The Management Of *Mutrashmari*

In 2019 Shri Gurudeo Ayurved College Gurukunj Ashram Amravati Maharashtra A Randomized Controlled Trial To Evaluate The Effect Of *Eranda Moola* (Root Of *Ricinus Communis*) In The Management Of Dyslipidemia

In 2018 Ch Brahm Prakash Ayurved *Charak Sansthan* Khera Dabar Najafgarh, New Delhi A Clinical Trial To Study The Effect Of Two Drugs, *Rasnadidashmool Kwatha* And *Erandadi Kwath* In Patients Of *Amavata* (Rheumatoid Arthritis)

In 2017 I.P.G.T & R.A., Jamnagar - Efficacy Of *Erandamula Niruha Vasti* And *Shunthi Kwath* With *Eranda Taila* In The Management Of *Katishool* (Lumbar Spondylosis): An Open Labelled Randomised Comparative Clinical Trial In The Year- 2017.

AIMS

To assess the efficacy of *Eranda Beeja Payas* in the management of *Gridhrasi* with special reference to *Sciatica*.

OBJECTIVES

1. To study the Ethiopathogenesis and Symptoms of the *Gridhrasi* with special reference to *Sciatica*.
2. To evaluate the efficacy of *Eranda Beeja Payas* in the management of *Gridhrasi* with special reference to *Sciatica*.
3. To re-evaluate the efficacy of *Rasanadi Guggul* in the management of *Gridhrasi* with special reference to *Sciatica*.
4. To compare the effect of *Eranda Beeja Payas* and *Rasanadi Guggul* with special reference to *Sciatica*.

HYPOTHESIS

❖ NULL HYPOTHESIS(H_0)

1. There is no significant effect of *Eranda Beeja Payas* in the management of *Gridhrasi* with special reference to *Sciatica*.

❖ ALTERNATE HYPOTHESIS (H_A)

H_{A1} : *Eranda Beeja Payas* is significantly effective than *Rasanadi Guggul* in the management of *Gridhrasi* with special reference to *Sciatica*.

H_{A2} : *Rasanadi Guggul* is significantly effective than *Eranda Beeja Payas* in the management of *Gridhrasi* with special reference to *Sciatica*.

REVIEW OF LITERATURE

❖ DISEASE REVIEW

Charaka Samhita:

- In 20th chapter of *Sutrasthana – Maharogadhaya*, *Gridhrasi* enumerated in 80 types of *Nanatmaja vatavyadhi*.
- IN 19TH chapter of *Sutrasthana – Astodariya Adhyaya*, description of two types of *Gridhrasi - Vataja and Vata- kaphaja* has been mentioned.(ch. Su. 19/7)
- IN 5TH chapter of *Sutrasthana, Matrashiteeya Adhyaya*, *Gridhrasi* is indicated with an indication of *Pada Abhyanga*. (ch. Su. 5/90)
- In 28th chapter of *Chikitsasthana – Vatavyadhi Chikitsa*, the detailed symptomatology and treatment of *Gridhrasi* have been given.^[6]

Sushruta Samhita:

- In *Sushruta Nidanasthana* 1st chapter, *Vatavyadhi Nidana*, symptomatology and pathology of *Gridhrasi* have been described. He mentioned a symptom “*Sakthikshepa Nigraha*” means unable to lift the leg straight as pain is produced as like SLR test in modern science. ^[8]
- In *Chikitsasthana* 5th chapter, *Mahavatavyadhi Chikitsa* and 8th chapter of *Sharirsathna* , *Siravedha chikitsa* for *Gridhrasi* is indicated. ^[7]

Ashtanga Hridaya:

- In *Nidhanasthana* 15th chapter *Vatavyadhi Nidana* symptomatology and pathogenesis of *Gridhrasi* is described.^[9]
- In *Sutrasthana* 27th chapter, site of *Siravedha* in *Gridhrasi* has been mentioned. ^[10]

Chakradatta:

- In *Chakradatta* *Gridhrasi* is explained in *Vatvyadhi Chikitsa*.^[11]

Yogaratanakara:

- In *Yogratanakra* symptomatology and classification of *Gridhrasi* has been mentioned under *Vatavyadhi Nidhana*. Few preparations have also been described in *Vatavyadhi chikitsa* which are useful in *Gridhrasi*. ^[12]

Madhava Nidana:

- In chapter *Vatavyadhi Nidana*, some specific symptoms of two types of *Gridhrasi* has been highlighted i.e. *Dehasya Pravakrat* (Sciatic scoliosis) in *Vataja* type, *Mukhapraseka* and *Bhaktadvesha* in *Vata- Kaphaja* type.

DRUG REVIEW:

The drug under consideration *Eranda Beeja Payas* has been taken from Bhaishajya Ratnavali Chapter no. 26 Vata Vyadhi Chikitsa Shloka no 42 ⁵

TABLE NO 1 (Eranda Beeja Payas)⁵

Reference: Bhaishajya Ratnavali

S.No.	INGREDIENT	LATIN NAME	RASA	GUNA	VIRYA	VIPAKA
1.	<i>Eranda</i>	<i>Ricinus communis</i>	<i>Madhura, Katu, Kashaya</i>	<i>Snigdha</i>	<i>Ushna</i>	<i>Madhura</i>
2.	<i>Shunthi</i>	<i>Zingiber officinale</i>	<i>Katu</i>	<i>Guru, Rookshna, Teekshna</i>	<i>Ushna</i>	<i>Madhura</i>

Action of Eranda Beeja Payas⁵:

S.No.	INGREDIENT	DOSHGHANTA	KARMA
1.	<i>Eranda</i>	<i>Kapha vata shamak</i>	<i>Vedana sthapak ,shoth har</i>
2.	<i>Shunthi</i>	<i>Kapha vata shamak</i>	<i>Vedana thapak,shoth har,vata anulomana</i>

TABLE NO 2 (*Rasana Guggul*)²¹

Reference : Yog Ratnakar

S.No.	INGREDIENT	LATIN NAME	RASA	GUNA	VIRYA	VIPAKA
1.	<i>Rasana</i>	<i>Pluchea lenceolata</i>	<i>Tikta</i>	<i>Guru</i>	<i>Ushna</i>	<i>Katu</i>
2.	<i>Guggul</i>	<i>Commiphora mukul</i>	<i>Tikta,katu</i>	<i>Laghu,Rukshna,Vishada,Suksham,Sara,Sugandi</i>	<i>Ushna</i>	<i>Katu</i>

Action of Rasana Guggul²¹:

S.No.	INGREDIENT	DOSHGHANTA	KARMA
1.	<i>Rasana</i>	<i>Kapha vata shamak</i>	<i>Shoth har,Vedana shamak,aampachak</i>
2.	<i>Guggul</i>	<i>Vata kapha shamak,medohar</i>	<i>Shoth har,Vedana sthapan,rakta kann vardak,rakta prasadana</i>

MATERIAL AND METHODS

1. Conceptual Study

Literary aspect of study will be collected from Classical Ayurvedic and contemporary text including the journals and website about the disease and drugs.

2. Clinical Study

- The patients of either sex, suffering from “*GRIDHRASI*” will be selected from OPD and IPD of Jammu Institute of Ayurveda and Research, Nardani and Urban wing, Janipur.

PLAN OF STUDY

- **Clinical Study** : For Clinical study, patient will be selected from OPD and IPD of Jammu Institute of Ayurveda and Research, Nardani and Urban wing, Janipur.
- **Type of Study** : A randomized, open labelled, comparative, pre and post test clinical study.
- **Level of Study** : O.P.D. & I.P.D. level.
- **Period of Study** : 18 months.

FOLLOW UP

- **Follow up (Group A & Group B)** :- on 15th day, 30th day and 45th day
- **Drug free Follow up (Group A & Group B)** :- on 45th day

SAMPLE SIZE

30 patients divided in 2 groups of 15 patients in each group.

❖ Grouping :

GROUP	DRUG	NO. OF PATIENTS
GROUP A (Trial Group)	<i>Eranda Beeja Payas</i>	15 patients
GROUP B (Comparative Group)	<i>Rasanadi Guggul</i>	15 patients

CRITERIA

INCLUSION CRITERIA: ¹³

1. Patients between the age group of 25 – 60 years.
2. Patient representing signs and symptoms of *Gridhrasi* who are willing to participate in study.
3. Subjects willing to participate with written informed consent, which is conveyed in the language which the subject can understand.
4. Both males and female will be selected.

EXCLUSION CRITERIA: ^[13]

1. Age below 25 years and above 60 years.
2. Patients suffering from Cardiac Diseases.
3. Uncontrolled Diabetes Mellitus, Hypertension.
4. Cancer of Lumbo-Sacral spine.
5. Tuberculosis of vertebral column.
6. Pregnant and lactating women.
7. Patient suffering from Ankylosing spondylitis, sacroiliac arthritis, herpes simplex infection causing radiating pain, disc prolapse, degenerative changes, bony osteophytic growth.
8. Any trauma related to Lumbo-sacral spine.

DRUG SELECTION AND PREPARATION

➤ **Collection of drug:**

Ingredients of trial drug *Eranda Beeja Payas*⁵ and *Rasanadi Guggul*²¹ will be procured from the authentic sources, identified and approved by Department of *Dravya Guna*, Jammu Institute of Ayurveda and Research, Jammu .

➤ **Preparation of drug:**

• **Trial drug:**

- Raw ingredients of trial drug *Eranda Beeja Payas*⁵ which contains *Eranda beeja* and *Shunthi* will be taken in equal parts.
- *Eranda Beeja* and *Shunthi* will be made into fine powder in the Pharmacy of, Department of *Rasa Shastra and Bhaishajya Kalpana*, Jammu Institute of Ayurveda and Research.
- *Eranda beeja churna* -12 gms⁵, *Shunthi churna*-12gms¹⁸ will be taken & *payas* will be prepared in accordance with the classical reference as mentioned in *Yogratnakar*¹⁹

[Note: The dose of the *Eranda Beeja Payas* depend upon the *Agni* of the patient²⁰]

• **Comparative drug:**

- Raw ingredients of Comparative drug *Rasanadi Guggul*²¹ which contains *Rasana* and *Guggul* will be made into *Vati* of 250 mg_ in the Pharmacy of Department of *Rasa Shastra and Bhaishajya Kalpana* ,Jammu Institute of Ayurveda

METHODS OF DATA COLLECTION

❖ **Randomization:-** Randomization will be done by using randomization software from www.randomizer.org .

❖ **Sampling Technique:-**

- Subjects will be randomized in two groups.
- A special Case Report Format (CRF) containing all the necessary details pertaining to the study will be prepared.
- Data obtained in the group will be recorded, tabulated and statistically analysed.

Interventions:-

Group A (Trial Group)

- **Yoga :-** *Eranda Beeja Payas*⁵
- **Dosage :-** According to *Agni*
- **Duration :-** 30 days
- **Follow up :-** on 15th day, 30th day and 45th day
- **Drug free Follow up :-** on 45th day

➤ **Group B (Comparative Group)**

- **Yoga :-** *Rasana Guggul vati*²¹
- **Dosage :-** 500mg BD with luke warm water
- **Duration :-** 30 days
- **Follow up :-** on 15th day, 30th day and 45th day
- **Drug free Follow up :-** on 45th day

ASSESSMENT CRITERIA:

For evaluating the efficacy of drugs, following parameters will be adopted before and after the completion of clinical trial.

SUBJECTIVE CRITERIA^[14]:

1. *TODA*
2. *RUK*
3. *STAMBHA*
4. *SPANDANA*
5. *GAURAVA*
6. *ARUCHI*
7. *TANDRA*

OBJECTIVE CRITERIA

1. VAS SCORE
2. SLR TEST
3. BRAGARD'S TEST

GRADING OF THE ASSESSMENT CRITERIA

1) *TODA* (PRICKING SENSATION) ¹⁴

GRADE	SCORE
No Pricking Sensation	0
Occasional Pricking Sensation	1
Mild Pricking Sensation (once a day)	2
Moderate Pricking Sensation (frequently in a day)	3
Severe Pricking Sensation (persistence)	4

2) *RUK* (Pain) ^[14]

GRADE	SCORE
No Pain	0
Occasional Pain	1
Mild Pain (No Difficulty in Walking)	2
Moderate Pain (Slight Difficulty in Walking)	3
Severe Pain (Severe Difficulty in Walking)	4

3) *STAMBHA* (STIFFNESS)^[14]

GRADE	SCORE
No stiffness	0
Stiffness for few minutes after sitting for long duration but relieved by mild movements	1
Stiffness more than 1 hour or more than once in a day but routine works are not disturbed.	2
Stiffness lasting for more than 1 hour or many times a day mildly affecting the daily routine.	3
Episodes of stiffness lasting for 2-6 hours. Daily routines are hampered severely	4

4) SPANDANA (FASICULATION) ^[14]

GRADE	SCORE
No <i>Spandana</i>	0
Sometimes for 5 to 10 minutes	1
Daily for 10 to 30 minutes	2
Daily for 30 – 60 minutes	3
Daily >1 hour	4

5) GAURAVA (HEAVINESS) ^[14]

GRADE	SCORE
No feeling of heaviness	0
Occasional feeling of heaviness not affecting the normal movements	1
Frequent feeling of heaviness affecting the normal movements	2
Feeling of heaviness throughout the day severely affecting the normal movements	3
Feeling of heaviness throughout the day totally Hampering normal movements	4

6) ARUCHI (ANOREXIA) ^[14]

GRADE	SCORE
Normal taste in food,feeling to eat food in time	0
Feeling to take food but not having taste	1
<i>Anannabhilasha</i> -Not feeling to take food even if hungry	2
<i>Bhaktadvesha</i> –aversion to food	3
<i>Abhaktachanda</i>	4

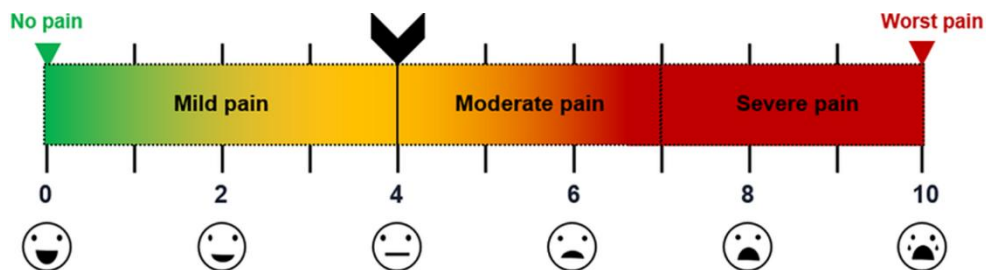
7) TANDRA(DROWSINESS) ^[14]

GRADE	SCORE
No <i>Tandra</i>	0
Mild <i>Tandra</i> occasionally but does not affect daily routine	1
Moderate <i>Tandra</i> frequently many times in a day that hampers daily routine	2
Moderate <i>Tandra</i> whole day and need to take rest, can not work	3
Severe <i>Tandra</i> whole day also at mental level,reduced alertness etc	4

OBJECTIVE CRITERIA GRADING:

- 1) **VAS SCORE** ^[15]: A visual Analogue Scale is a uni-dimensional measure of intensity of pain and used to record the progression of pain also compare the severity of pain between the patients

PAIN SCORE	GRADE	VAS SCORE
0	No pain	0
1	Mild pain	1-3
2	Moderate pain	4-7
3	Severe pain	8-10



- 2) **Straight leg raising test (S.L.R.)** ^[16]

S.L.R.	GRADE
More than 90 degree	0
71degree-90 degree	1
51degree-70 degree	2
31degree-50 degree	3
Up to 30 degree	4

3) Bragard's Test^[17]

Bragard's Test	Grading
Absent	0
Mildly Positive	1
Moderately Positive	2
Highly Positive	3

INVESTIGATIONS:

LABORATORY INVESTIGATIONS [To rule out other ailments]

- Hb gm%
- ESR
- Blood Sugar

CRITERIA FOR OVERALL EFFECT OF THERAPY:

The result will be categorized as :-

Complete Remission	100% relief in the subjective and objective parameter
Marked Improvement	More than 76% relief in the subjective and objective parameter
Moderate Improvement	51 to 75% relief in the subjective and objective parameter
Mild Improvement	26 to 50% relief in the subjective and objective parameter
Unchanged	Result below 25% was considered as unchanged

CONCLUSION:

- Conclusion will be made on the basis of observation which is done on subjective and objective parameters
- Result will be analysed statistically and discussed accordingly

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