



INSTITUTIONAL ETHICAL COMMITTEE

Surendera Dental College and Research Institute
H.H. Gardens, Power House Road
Sri Ganganagar, Rajasthan,
India, 335001



Patron:

Mr. Suraj Aggarwal
(Chairman, SDC&RI)

Mr. Gorav Gupta
(Managing Director, SDC&RI)

Dr. Sandeep Kumar
(Director Principal, SDC&RI)

Chairman:

Dr. Parveen Kumar

Member Secretary:

Dr. Seema Gupta

Basic Medical Scientist:

Dr. A.P.Dadhich

Clinician:

Dr. Rajnish Aggarwal

Advocate:

Sh. Surender Singh Bhanot

Social Scientist:

Mr. Jju Rani

Lay Person:

Mr. Gurmeet Singh

Members:

Dr. Manisha Solanki

Dr. Basavraj T Bhagawati

Dr. Eenal Bhambrri

Dr. Rajni Aggarwal

Dr. Renu Aggarwal

Dr. Suruchi Juneja

Dr. Manu Batra

Dr. Manish Sharma

Dr. Charanpreet Kaur

No. : SDCRI/IEC/21/03

Date: 27/07/2021

To,

Dr. Deepika Choudhary

1st year PG Student

Dept. of Periodontology & Oral Implantology

Surendera Dental College & Research Institute

Sri Ganganagar

Rajasthan

India-335001

Subject: Approval of the clinical study – “TO EVALUATE THE CLINICAL EFFICACY OF 940MM DIODE LASER AND PROPOLIS GEL IN ADJUNCT TO SRP IN TREATMENT OF CHRONIC PERIODONTITIS”.

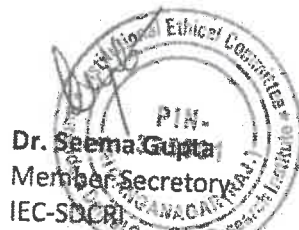
Dear Dr. Deepika,

The Institutional Ethical Community has reviewed and discussed your application to conduct the above mentioned clinical trial with yourself as the Principal investigator. We approve the trial to be conducted in the presented form. None of the Investigator and co-investigator participating in this study took part in the decision making and voting procedure for this study.

The institutional Ethics committee expects to be informed about the progress of the study, and any revision in the protocol.

This Ethics committee is working in accordance to ICMR guidelines.

Yours Sincerely,



Dr. Seema Gupta

Member Secretary


IEC-SDCRI

Surendera Dental College & Research Institute

Sri Ganganagar-335001

(File No. EC/NEW/INST/2020/731)

Received
Deepika


DIRECTOR PRINCIPAL
SURENDERA DENTAL COLLEGE
& RESEARCH INSTITUTE
SRI GANGANAGAR (RAJ)

From

Dated:15/07/2021

Dr. DEEPIKA CHOUDHARY,
1st Year P.G. Student,
Department of Periodontology & Oral Implantology,
Surendera Dental College & Research Institute,
SriGanganagar, Rajasthan

To

The Chairman, Ethical Committee,
Surendera Dental College & Research Institute,
SriGanganagar, Rajasthan.

Through

The Head of Department,
Department of Periodontology & Oral Implantology,
Surendera Dental College & Research Institute,
SriGanganagar, Rajasthan

Subject: -Application for issuing Institutional Ethical Committee clearance certificate for my proposed work.

Respected sir,

With due respect, I Dr DEEPIKA CHOUDHARY, 1st year PG student of Department of Periodontology & Oral Implantology, request you to issue me the certificate of institutional ethical committee clearance to start my MDS Library Dissertation titled **"TO EVALUATE THE CLINICAL EFFICACY OF 940nm DIODE LASER AND PROPOLIS GEL IN ADJUNCT TO SRP IN TREATMENT OF CHRONIC PERIODONTITIS."** for completion of my M.D.S course. A copy of synopsis of my work is attached herewith for your consideration.

Thanking you in anticipation

Yours sincerely,

Dr. DEEPIKA CHOUDHARY,
PG student 1st year
Department of Periodontology & Oral Implantology,
Surendera Dental College & Research Institute.
Sriganganagar, Rajasthan.



Rajni
Signature
Head of Department
Sri Ganganagar

Received Rs. 200/-
On 16-07-2021
Receipt no. 335503

Forwarded to Dr. Renu

17/7/21

dy
DIRECTOR PRINCIPAL
SURENDERA DENTAL COLLEGE
& RESEARCH INSTITUTE
SRI GANGANAGAR (RAJ.)

Surendera Dental College & Research Institute

Surendera Dental College & Research Institute
Communication of Decision of the Institutional Ethics Committee (IEC)
(Fields 1,2 and 3 to be filled by investigators)

IEC No: 2022-23-001

1. Protocol title TO EVALUATE THE CLINICAL EFFICACY OF 940NM DIODE LASER AND PROPOLIS WEL IN ADJUNCT TO SRP IN TREATMENT OF CHRONIC PERIODONTITIS.		
2. Principal Investigator: DR. DEEPIKA CHOUDHARY		
3. Name & Address of Institution: SURENDERA DENTAL COLLEGE AND RESEARCH INSTITUTE, SRI GANGANAGAR, RAJASTHAN		
<input type="checkbox"/> New review	<input type="checkbox"/> Revised review	<input type="checkbox"/> Expedited review
Date of review (D/M/Y):		
Date of previous review, if revised application:		
Decision of the IEC/ IRB:		
<input type="checkbox"/> Recommended	<input type="checkbox"/> Recommended with suggestions	
<input type="checkbox"/> Revision	<input type="checkbox"/> Rejected	
Suggestions/ Reasons/ Remarks:		
Recommended for a period of :		


Please note *

- Inform IEC immediately in case of any adverse events and serious adverse events.
- Inform IEC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above. Annual report to be submitted to IEC.
- Members of IEC have right to monitor the trial with prior intimation.


Principal
SDCRI


Chairman
IEC

Member Secretary
IEC


DIRECTOR PRINCIPAL
SURENDERA DENTAL COLLEGE
& RESEARCH INSTITUTE
SRI GANGANAGAR (RAJ)

Surendera Dental College & Research Institute

Surendera Dental College & Research Institute
Institutional Ethics Committee Review Form

Serial No of IEC (to be filled by IEC Office): _____

-----To be filled by Investigators-----

Proposal Title: TO EVALUATE THE CLINICAL EFFICACY OF 940nm DIODE LASER AND PROPOLIS

Principal Investigator: MEL IN ADJUNCT TO SRP IN TREATMENT OF CHRONIC PERIODONTITIS.

Co-investigator: DR. DEEPIKA CHOUDHARY

1. DR. RAJANI AGARWAL

2.

3.

Supporting Agency: ICMR/ non ICMR

If non ICMR, name of agency: _____

-----To be filled by reviewer-----

Project Status: New Revised

Review: Regular Interim

Date of Review: 26/7/21

1. Research Design


- i. Scientifically sound enough to expose subjects to risk Yes No
- ii. Relevant to contribute to further knowledge Yes No
- iii. Of national importance Yes No

2. Risks

- a. Is there physical/social/psychological risk/discomfort? Yes No
- b. Is the overall risk/benefit ratio Acceptable Unacceptable

3. Benefits

- Direct: Reasonable Undue None
- Indirect: Improvement in Science/knowledge Any other


DIRECTOR PRINCIPAL
SURENDERA DENTAL COLLEGE
& RESEARCH INSTITUTE
SRI GANGANAGAR (RAJ.)

Surendera Dental College & Research Institute

4 Subject selection :

- i Inclusion / exclusion criteria addressed? Yes No
- ii Vulnerable subjects (woman, child, mentally challenged, Seriously or terminally ill, foetus, economically or socially Backward and healthy volunteers) adequately protected? Yes No
- iii. Special group subjects (captives, students, nurses & Dependant staff) adequately protected? Yes No

5 Privacy & Confidentiality maintained? Yes No

6 Patient Information Sheet: Adequate Inadequate

7. Consent form components addressed adequately? Yes No

8. Compensation, (if applicable) addressed adequately? Yes No

9. Is there a Conflict of Interest? Yes No

If yes,

Acceptable Unacceptable

10. Budget: Appropriate Inappropriate

11. Decision of review

- Recommended Recommended with suggestions
- Revision Rejected

Any other remarks/suggestions:

*Okay - good. Clinical Study.
increase the Treatment of
Chronic Periodontitis*

Reviewers names and Signatures

Dr. Renu Aggarwal.

*Renu
26/7/21.*

[Signature]
DIRECTOR PRINCIPAL
SURENDERA DENTAL COLLEGE
& RESEARCH INSTITUTE
SRI GANGANAGAR (RAJ)

Surendera Dental College & Research Institute Sri Ganganagar

Serial No of IEC: _____

(To be filled by IEC office)

Proposal Title: TO EVALUATE THE EFFICACY OF QUOTM DIODE LASER AND PROPOLIS GEL IN ADJUNCT TO SRP IN TREATMENT OF CHRONIC PERIODONTITIS

	Name, Designation & Qualifications	Address Tel & Fax Nos. Email ID	Signature
PI	Dr. DEEPIKA CHAUDHARY BDS, MDS I st yr	SURENDERA DENTAL COLLEGE & RESEARCH INSTITUTE, SGNR 335001 → 7728914303 dr.deepikachoudhary@gmail.com	
Co-PI/ Collaborators	Dr. RAJNI AGARWAL PROFESSOR & HEAD SURENDERA DENTAL COLLEGE	SURENDERA DENTAL COLLEGE & RESEARCH INSTITUTE, SGNR, 335001 → 7627071275	
1.	NA		
2.			
3.	NA		

Tick appropriately

Sponsor Information :

1. Indian a) Government Central State Institutional

b) Private

2. International Government Private UN agencies

3. Industry National Multinational

Contact Address of Sponsor(if applicable):

SURENDERA DENTAL COLLEGE AND RESEARCH INSTITUTE, SRI GANGANAGAR
RAJASTHAN.


Total Budget (if applicable/sponsored) :NOT APPLICABLE

1.Type of Study : Epidemiological Basic Sciences Animal studies
 Clinical: Single center Multicentric Behavioral

DIRECTOR PRINCIPAL
 SURENDERA DENTAL COLLEGE
 & RESEARCH INSTITUTE
 SRI GANGANAGAR (RAJ)


Surendera Dental College & Research Institute Sri Ganganagar

2. Status of Review:		New <input checked="" type="checkbox"/>	Revised <input type="checkbox"/>
3. Clinical Trials:			
Drug /Vaccines/Device/Herbal Remedies :			
i. Does the study involve use of :			
Drug	Devices	Vaccines	<input type="checkbox"/>
Indian Systems of Medicine/ Alternate System of Medicine	Any other	NA	<input checked="" type="checkbox"/>
ii. Is it approved and marketed			
In India	UK & Europe	USA	<input checked="" type="checkbox"/>
Other countries, specify <input type="checkbox"/>			
iii. Does it involve a change in use, dosage, route of administration?		Yes	No <input checked="" type="checkbox"/>
If yes, whether DCGI's /Any other Regulatory authority's Permission is obtained?		Yes	No
If yes, Date of permission :			
iv. Is it an Investigational New Drug?		Yes	No <input checked="" type="checkbox"/>
If yes, IND No:			
a). Investigator's Brochure submitted		Yes	No
b). <i>In vitro</i> studies data		Yes	No
c). Preclinical Studies done		Yes	No
d). Clinical Study is : Phase I <input type="checkbox"/> Phase II <input type="checkbox"/> Phase III <input type="checkbox"/> Phase IV <input type="checkbox"/>			
e). Are you aware if this study/similar study is being done elsewhere ?		Yes	No <input checked="" type="checkbox"/>
If Yes, attach details			
4. Description of the proposal – Introduction, review of literature, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it is of national significance with rationale : ATTACHED SYNOPSIS COPY			
5. Privacy and confidentiality			
i. Study involves -			
Direct Identifiers		<input checked="" type="checkbox"/>	
Indirect Identifiers/coded		<input type="checkbox"/>	
Completely anonymised/ delinked		<input type="checkbox"/>	
i. Confidential handling of data by staff		Yes <input checked="" type="checkbox"/>	No


 DIRECTOR PRINCIPAL
 SURENDERA DENTAL COLLEGE
 & RESEARCH INSTITUTE
 SRI GANGANAGAR (RAJ.)

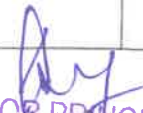
Surendera Dental College & Research Institute Sri Ganganagar

6. Use of biological/ hazardous materials	Yes	No
i. Use of fetal tissue or abortus		<input checked="" type="checkbox"/>
ii. Use of organs or body fluids	Yes	No <input checked="" type="checkbox"/>
iii. Use of recombinant/gene therapy	Yes	No <input checked="" type="checkbox"/>
If yes, has Department of Biotechnology (DBT) approval for rDNA products been obtained?	Yes	No
iii. Use of pre-existing/stored/left over samples	Yes <input checked="" type="checkbox"/>	No
v. Collection for banking/future research	Yes	No <input checked="" type="checkbox"/>
vi. Use of ionising radiation/radioisotopes	Yes	No <input checked="" type="checkbox"/>
If yes, has Bhaba Atomic Research Centre (BARC) approval for Radioactive Isotopes been obtained?	Yes	No
vii. Use of Infectious/biohazardous specimens	Yes	No <input checked="" type="checkbox"/>
viii. Proper disposal of material	Yes <input checked="" type="checkbox"/>	No
ix. Will any sample collected from the patients be sent abroad ?	Yes	No <input checked="" type="checkbox"/>
If Yes, justify with details of collaborators		
a) Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?	Yes	No
b) Sample will be sent abroad because (Tick appropriate box):		
Facility not available in India		<input type="checkbox"/>
Facility in India inaccessible		<input type="checkbox"/>
Facility available but not being accessed.		<input type="checkbox"/>
If so, reasons...		


DIRECTOR PRINCIPAL
SURENDERA DENTAL COLLEGE
& RESEARCH INSTITUTE
SRI GANGANAGAR (RAJ)

Surendera Dental College & Research Institute Sri Ganganagar

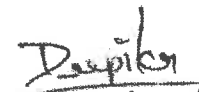
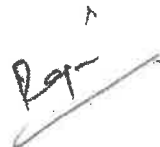
7. Consent : *Written <input checked="" type="checkbox"/> Oral <input type="checkbox"/> Audio-visual <input type="checkbox"/>		
i. Consent form : (tick the included elements)		
Understandable language <input checked="" type="checkbox"/> Statement that study involves research <input checked="" type="checkbox"/> Sponsor of study <input checked="" type="checkbox"/> Purpose and procedures <input checked="" type="checkbox"/> Risks & Discomforts <input checked="" type="checkbox"/> Benefits <input checked="" type="checkbox"/> Compensation for participation <input type="checkbox"/> Compensation for study related injury <input type="checkbox"/>	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Alternatives to participation <input type="checkbox"/> Confidentiality of records <input type="checkbox"/> Contact information <input type="checkbox"/> Statement that consent is voluntary <input type="checkbox"/> Right to withdraw <input type="checkbox"/> Consent for future use of biological material <input type="checkbox"/> Benefits if any on future commercialization eg. genetic basis for drug development <input type="checkbox"/>
*If written consent is not obtained, give reasons:		
ii. Who will obtain consent ? PI/Co-PI <input checked="" type="checkbox"/> Nurse/Counsellor <input type="checkbox"/> Research staff <input type="checkbox"/> Any other <input type="checkbox"/>		
8. Will any advertising be done for recruitment of Subjects? (posters, flyers, brochure, websites – if so kindly attach a copy)	Yes	No <input checked="" type="checkbox"/>
9. Risks & Benefits:		
i. Is the risk reasonable compared to the anticipated benefits to subjects / community / country?	Yes	No <input checked="" type="checkbox"/>
ii. Is there physical / social / psychological risk / discomfort? If Yes, Minimal or no risk <input type="checkbox"/> More than minimum risk <input type="checkbox"/> High risk <input type="checkbox"/>	Yes	No <input checked="" type="checkbox"/>
iii. Is there a benefit a) to the subject ? Direct <input type="checkbox"/> Indirect <input type="checkbox"/> b) Benefit to society <input type="checkbox"/>		
10. Data Monitoring		
i. Is there a data & safety monitoring committee/ Board (DSMB)?	Yes	No
ii. Is there a plan for reporting of adverse events ? If Yes, reporting is done to : Sponsor <input type="checkbox"/> Ethics Committee <input type="checkbox"/> DSMB <input checked="" type="checkbox"/>	Yes	No
iii. Is there a plan for interim analysis of data?	Yes	No <input checked="" type="checkbox"/>
vi. Are there plans for storage and maintenance of all trial database? If Yes, for how long ?	Yes	No <input checked="" type="checkbox"/>
11. Is there compensation for participation? If Yes, Monetary <input type="checkbox"/> In kind <input type="checkbox"/>		
Specify amount and type:		


 DIRECTOR PRINCIPAL
 SURENDERA DENTAL COLLEGE
 & RESEARCH INSTITUTE
 SRI GANGANAGAR (RAJ)

Surendera Dental College & Research Institute Sri Ganganagar

12. Is there compensation for injury? If Yes, by Sponsor <input type="checkbox"/> by Investigator <input type="checkbox"/> by insurance <input type="checkbox"/> by any other <input type="checkbox"/> company	Yes	No ✓
13. Do you have conflict of interest? (financial/nonfinancial) If Yes, specify :	Yes	No ✓
Checklist for attached documents:		
Project proposal – 2 Copies (1hard/1soft on CD)	<input type="checkbox"/>	
Patient information sheet	<input type="checkbox"/>	
Informed Consent form	<input type="checkbox"/>	
Investigator's brochure for recruiting subjects	<input type="checkbox"/>	
Copy of advertisements/Information brochures	<input type="checkbox"/>	
Copy of clinical trial protocol and/or	<input type="checkbox"/>	
questionnaire	<input type="checkbox"/>	
Institutional Animal Ethics Committee clearance	<input type="checkbox"/>	
CPCSEA clearance, if any	<input type="checkbox"/>	
HMSC/DCGI/DBT/BARC clearance if	<input type="checkbox"/>	
Obtained		

Place: SRIGANGANAGAR
Date:


 (MDS 1st yr) (Dept of pedo) 
 Signature & Designation of PI/Co-PI/Collaborator


DIRECTOR PRINCIPAL
SURENDERA DENTAL COLLEGE
& RESEARCH INSTITUTE
SRI GANGANAGAR (RAJ.)


**SURENDERA DENTAL COLLEGE AND RESEARCH
INSTITUTE
SRIGANGANAGAR**

CONSENT FORM

I , age/sex , OPD no. , hereby declare that I have been informed about the study which is being conducted in Department of Periodontology & Oral implantology, Surendera Dental College And Research Institute, Sri Ganganagar and fully understand that I shall have to undergo a minor surgical procedure involving reflecting of a mucoperiosteal flap in the oral cavity. I have been explained about the complete procedure in my language. I do not have any objection and hereby grant permission for the same.

Signature of Patient/Parent/Guardian


Address:


DIRECTOR PRINCIPAL
SURENDERA DENTAL COLLEGE
& RESEARCH INSTITUTE
SRI GANGANAGAR (RAJ.)

RAJASTHAN UNIVERSITY OF HEALTH SCIENCES, JAIPUR

**PROFORMA FOR REGISTRATION OF SUBJECTS FOR DISSERTATION OF
MDS**

1.	NAME OF THE CANDIDATE AND ADDRESS (in block letters)	DR. DEEPIKA CHOUDHARY MDS 1 ST YEAR DEPARTMENT OF PERIODONTOLOGY & ORAL IMPLANTOLOGY SURENDERA DENTAL COLLEGE AND RESEARCH INSTITUTE, H.H GARDENS, SRIGANGANAGAR, RAJASTHAN PIN CODE -335001
2.	NAME OF THE INSTITUTION	SURENDERA DENTAL COLLEGE AND RESEARCH INSTITUTE, H.H GARDENS, SRIGANGANAGAR, RAJASTHAN PIN CODE -335001
3.	COURSE OF STUDY AND SUBJECT	MASTERS IN DENTAL SURGERY (MDS) PERIODONTOLOGY
4.	DATE OF ADMISSION	JUNE 2020
5.	TITLE OF THE TOPIC	To evaluate the clinical efficacy of 940nm diode laser and propolis gel in adjunct to SRP in treatment of chronic periodontitis.



DIRECTOR PRINCIPAL
SURENDERA DENTAL COLLEGE
& RESEARCH INSTITUTE
SRI GANGANAGAR (RAJ)

Need for the study

One of the most common afflictions of mankind in terms of global prevalence are Periodontal diseases. The initiation and progression of periodontal diseases are closely associated with pathogenic bacteria present in the sub gingival biofilm.¹ Traditionally, chronic periodontitis (CP) is treated by scaling and root planning (SRP) in which dental plaque and calculus deposits are removed from supra- and subgingival teeth and root surfaces using hand instruments (such as curettes and scalers).^{2,3} Although SRP reduces periodontal inflammation to an extent, this treatment approach is unable to completely eradicate periodontal disease. An explanation for this is the incomplete removal of epithelium and persistence of periodontal pathogenic bacteria (such as *Aggregatibacter actinomycetemcomitans* and *Porphyromonas gingivalis*) in sites (such as gingival epithelium) inaccessible by hand instruments.⁴ It has also been reported that the outcomes of SRP is dependent on the manner in which SRP is performed.

Recently, in general dental practice, Laser technology, specifically the diode laser is gaining popularity with potential benefits in a wide range of applications. Since it is portable, convenient to use, good tissue penetration, good hemostasis, sterilization and minimal postoperative pain when compared to conventional surgical procedures and is well absorbed in pigmented tissues, it can specifically target the pigmented bacteria and granulation tissue. In vitro evaluation has shown the diode laser to achieve a more complete elimination of the epithelial lining of the periodontal pocket.⁶

This trend, in addition to the high cost of synthetic medicines and the consumers' Many antibacterial agents have been tested for intra pocket delivery including tetracycline, doxycycline, minocycline, chlorhexidine, and metronidazole, but none are without side effects. To overcome the side effects of synthetic artificial drugs, various natural products has led to a growing world market for phytotherapy. Herbal extract has an advantage of cost-effectiveness, minimal side effect, and good patient compliance. Natural products, including propolis, are now frequently used to combat periodontal disease and decay.⁷ According to the technical regulations of the Agricultural Ministry, propolis is a hive product that bees manufacture from balsamic resins actively secreted by plants on leaf buds and barks. The bees increase salivary secretions, wax and pollen for final elaboration of the product.⁸ Propolis has been used for thousands of years,


DIRECTOR PRINCIPAL
SURENDRA DENTAL COLLEGE
& RESEARCH INSTITUTE
SRI GANGANAGAR (RAJ.)

credited with biological activity that is antibacterial, antiviral, antitumoral, immunomodulatory and anti-inflammatory.⁹

Thus, the present study is designed to evaluate the clinical efficacy of diode laser(940nm), propolis gel and SRP in treatment of Chronic Periodontitis.

AIM AND OBJECTIVE OF THE STUDY:

To evaluate the clinical efficacy of 940nm diode laser, propolis gel and SRP in treatment of Chronic Periodontitis.

Objective:

1. To evaluate the clinical efficacy of scaling and root planning effect in therapeutic association in respect of chronic periodontitis.
2. To evaluate the clinical efficacy of SRP + 940nm Diode Laser in reduction of chronic periodontitis.
3. To evaluate the clinical efficacy of SRP + Propolis Gel in reduction of chronic periodontitis.

MATERIALS AND METHODS


SELECTION CRITERION:

INCLUSION CRITERION:

1. Thirty volunteered individuals with moderate to severe chronic periodontitis, each with at least three pockets 4–7mm deep.
2. Patients who are non-smokers
3. Patients without any known systemic disorder/disease.
4. No prescribed antibiotics and/or anti-inflammatory medications used by patient in the last 3 months
5. All patients having appropriate cooperation.
6. Patients willing to follow the study protocol.

EXCLUSION CRITERION:

1. Medically compromised patients.


DIRECTOR PRINCIPAL
SURENDRA DENTAL COLLEGE
& RESEARCH INSTITUTE
SRI GANGANAGAR (RAJ.)

2. Patients having severe parafunctional habits (bruxism or clenching etc).
3. Patients having adverse habits (eg. drugs/ alcohol abuse, smoking etc).
4. Patients having blood diseases/ disorder that prevent centrifugation.
5. Pregnant and lactating patients.
6. Patients having allergy to the materials to be used during procedures.
7. Patients who are not maintaining meticulous oral hygiene.

CLINICAL PARAMETERS:

- Full mouth Plaque Index (Sillness J and Loe H).
- Full mouth gingival index (Loe H and Silness J).
- Papillary bleeding index (PBI) mean score
- Clinical attachment level (CAL)
- Pocket probing depth (PPD)

RADIOGRAPHICAL PARAMETERS:


- Marginal bone level on IOPA X Ray

STUDY MATERIAL AND EQUIPMENT REQUIRED:

- PMT set – Periodontal probe, mouth mirror, tweezers, explorer
- 10ml disposable syringes
- Chlorhexidine mouthwash for presurgical rinse
- IOPA X-ray
- Propolis Gel
- Diode Laser (980nm) wavelength

STUDY DESIGN

Patients who fulfilled the above mentioned criterion will be shortlisted for the trial from the Out-Patient Department of Periodontology and Implantology of


DIRECTOR PRINCIPAL
SURENDRA DENTAL COLLEGE
& RESEARCH INSTITUTE
SRI GANGANAGAR (RAJ.)

Surendera Dental College and Research Institute, Sriganganagar. All the patients will be duly explained about the trial protocol with their pros and cons. Informed consent (in Hindi and English language) will be explained to the patient and duly signed by the patients.

A standardized protocol for each site will be strictly adhered to.

This will include the principles of case selection, case evaluation, proper planning, pre-operative preparation, surgical procedure and post-operative care.

Thirty patients with moderate to severe chronic periodontitis, each with at least three pockets 4-7mm deep, will be selected for this study. The patients will be selected randomly and treated by either scaling and root planning (SRP) alone, or by SRP + diode laser (1.5 W, 940nm, 30sec, continuous wave) (laser group), or by SRP + propolis gel (gel group).

The selected sites will be categorized as:

Group A: Control site which consists of 10 patients will be treated by SRP alone.

Group B. Test site 1 - which consists of 10 patients will be treated by LASER + SRP.

Group C: Test site II- which consists of 10 patients will be treated by PROPOLIS GEL + SRP.

Due cognizance will be paid for comprehensive medical and dental history with the use of preprinted, standardized, self-administered questionnaire.

Then, the basic principle of health care to sign the consent form will be accomplished by giving sufficient information about the proposed treatment protocol and the possible alternatives.

Patient preparation will include Phase I therapy, motivation and encouragement for new oral hygiene regimen until satisfactory level of care is achieved.

Oral disinfection will be performed using a 0.2 % Chlorhexidine digluconate mouthwash.

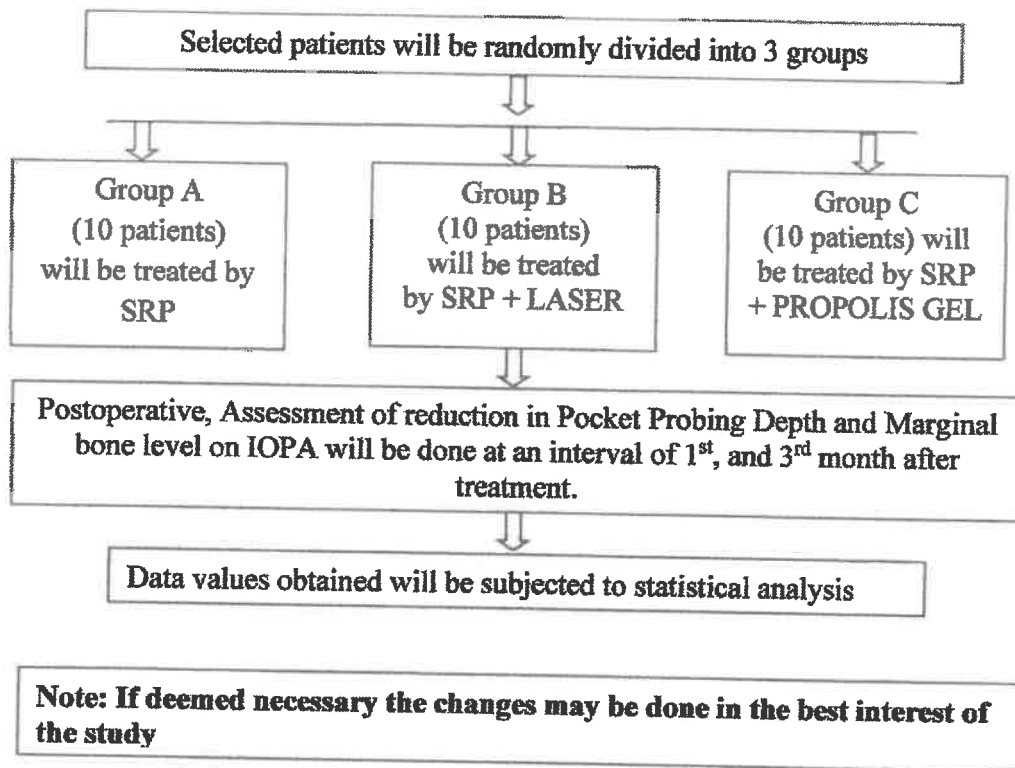
Minimal 30 Patients visiting Department of Periodontology with chief complaint of Chronic Periodontitis



Patients fulfilling the inclusion and exclusion criterion and will submit written informed consent after listening to clinician about the pros and cons of treatment to be selected for study




DIRECTOR PRINCIPAL
SURENDERA DENTAL COLLEGE
& RESEARCH INSTITUTE
SRI GANGANAGAR (RAJ)



METHOD OF COLLECTION OF DATA:

CLINICAL PARAMETERS:

Full mouth Plaque index, *gingival index, Papillary bleeding index (PBI) mean score, Clinical attachment level (CAL), Pocket probing depth (PPD) as described in the study design, values will be comparatively evaluated as per the study protocol.


RADIOLOGICAL PARAMETERS:

Intraoral radiographs using paralleling technique will be taken to ensure that the marginal bone loss changes will be observed if any.

Does the study require any investigations or interventions to be conducted on patients or other humans or animals? If so, please described brief.


Yes

LIST OF REFERENCES:


 DIRECTOR PRINCIPAL
 SURENDRA DENTAL COLLEGE
 & RESEARCH INSTITUTE
 SRI GANGANAGAR (RAJ)

1. Holt S.C., Ebersole J.L. Porphyromonas gingivalis, treponema denticola, & tannerella forsythia: 'the red complex', a prototype polybacterial pathogenic consortium in periodontitis. Periodontol 2000.2005;38:72-122.
2. Aimetti M. Nonsurgical periodontal treatment. Int J Esthet Dent 2014;9(2):251-67.
3. Ince G, Gursoy H, Ipci S.D., Cakar G, Emekli-Alturfan E, Yilmaz S. Clinical and biochemical evaluation of lactobacillus reuteri containing lozenges as an adjunct to non-surgical periodontal therapy in chronic periodontitis. J Periodontol 2015;86:746-54.
4. Saglie F.R., Smith C.T., Newman M.G. The presence of bacteria in the oral epithelium in periodontal disease. II. Immunohistochemical identification of bacteria. J Periodontol 1986;57(8):492-500.
5. Aoki A. et al. Current status of clinical laser applications in periodontal therapy. Gen Dent. 2008;57(1):94.
6. Wigdor H.A., Walsh J.T. Jr, Featherstone J.D., Visuri S.R., Fried D, Waldvogel J.L. Lasers in dentistry. Lasers Surg Med 1995;16:103-33.
7. Grunwald J. The European phytomedicines market: Figures, trends, analysis. Herbalgram 1995;34:60-5.
8. Koo H, Gomes B.P., Rosalen P.L., Ambrosano G.M., Park Y.K., Cury J.A. In vitro antimicrobial activity of propolis and Arnica montana against oral pathogens. Archives of Oral Biology 2000;45:141-8.
9. Grunberger et al. Preferential cytotoxicity on tumor cells by caffeic acid phenethyl ester isolated from propolis. Experientia 44. 1988;230-2.

9.	SIGNATURE OF CANDIDATE	
10.	REMARKS OF GUIDE	


DIRECTOR PRINCIPAL
SURENDRA DENTAL COLLEGE
& RESEARCH INSTITUTE
SRI GANGANAGAR (RAJ)

12.	12.1 REMARK OF THE DIRECTOR & PRINCIPAL 12.2 SIGNATURE	
-----	---	--


DIRECTOR PRINCIPAL
SURENDRADENTAL COLLEGE
& RESEARCH INSTITUTE
SRI GANGANAGAR (RAJ.)