

Indian Science Technology and Engineering facilities Map (I-STEM)

Invites application for

1. **Partial financial support for using R&D facilities in other institutions through the I-STEM web portal to Users from Academic Institutions and Start-ups (Format-1)**

Format for requesting support for accessing and using facilities through the I-STEM web portal.

(i) Details of the Personal Information

- a. Name of the Researcher/Faculty Member-Dr. Swapna Arunkumar Mahale
- b. Name of the Institution/Start-up-MGV's KBH Dental College and Hospital, Nashik
- c. Name of the Department-Dental-Periodontology
- d. Degree registered for/Product being developed (for start-up)-Pursuing PhD, at Datta Meghe institute of medical sciences- Sawangi, Wardha
- e. Mob. No.9422764080
- f. Email ID: drsamahale@gmail.com

(ii) Project/Research topic Details:

a. Project Title/Research Title: Assessment and comparison of the antimicrobial and clinical efficacy of copper nanoparticles gel with scaling and root planing (SRP) against chlorhexidine gel with scaling and root planing (SRP) as a local drug delivery agent in patients with periodontitis –A randomized interventional clinical trial.

b. Sub area: Periodontics\Dental\Microbiology.

c. Area Description: Cu NPs exhibits excellent antiviral behavior as found to inactivate virus through inhibiting its RNA replication while its protein shell remained intact, which suggests that ions penetrated into the virus to act against the RNA. In addition to direct killing, NPs modulates immune responses, and enhances innate antimicrobial immune defenses. Phagocyte-derived reactive oxygen and nitrogen species remain vital for the host to fight against infective pathogens. Nitric oxide gets oxidized to Cu, present in protective proteins in microbes, to free Cu ions, which boosts toxicity to microbial cells.

d. Aims & Objective (in Bullets):

- Aim-To assess and compare the antimicrobial efficacy of copper nanoparticles gel with SRP against chlorhexidine gel with SRP on clinical outcomes as a local drug delivery agent in patients with periodontitis.
- Objectives- To assess the following parameters of copper nanoparticles against Periodontal pathogens(Porphyromonas gingivalis, P. intermedia, F. nucleatum, Tannerella forsythia, and Actinobacillus actinomycetemcomitans.)
 1. To assess the antimicrobial activity.
 - 2.To assess cell viability (MTT assay) for its efficacy.
 - 3.To assess Safety and dose determination of the prepared copper nanoparticle gel

- 4.To assess Time kill assay for copper nanoparticle gel
- 5.To assess Anti-biofilm formation for copper nanoparticle gel
- 6.To assess Biocompatibility study with cell line for copper nanoparticle gel

Duration (MM/YYYY): 6-8 months

Project Summary (1000 words):

Contact person: Dr. Swapna Mahale. Ph no: +91 9422764080.

Purpose: To appraise the antimicrobial, cytotoxicity, time kill assay and physical properties of Cu nanoparticle gel against periodontal pathogens.

Description: Copper nanoparticles prepared by biological synthesis are cost-effective and eco-friendly as compared to their chemical counterparts.

Rationale: Nanotechnology furnishes an opportunity to resolve antibiotic resistance of microbes to drugs. The introduction of copper fittings, and work surfaces acts as an additional blockade because of its ability to speedily eradicate MRSA to prevent cross-contamination. Copper represents two ends of the viability spectrum for micro-organisms, being both an essential nutrient at one end but also highly toxic at the other end. The metals used for these NPs are almost exclusively heavy metals, such as Cu. A necessity for efficacious clinical trial is required to estimate the usefulness in conjunction with the safety.

e. **Technical Details**

a.TRL: Nanotechnology furnishes an opportunity to resolve antibiotic resistance of microbes to drugs. Nanoparticles tackle “common antibiotic resistance mechanisms like regulation of permeability, multi-drug efflux pumps, antibiotic degradation and target site binding affinity mutations”. Copper represents two ends of the viability spectrum for micro-organisms, being both an essential nutrient at one end but also highly toxic at the other end. The metals used for these NPs are almost exclusively heavy metals, such as Ag and Cu. A necessity for efficacious clinical trial is required to estimate the usefulness in conjunction with the safety. The current information on NPs inspires that further research should be conducted to invent the potential applications of NPs in the controlling of dental infections.

b.Methodology: A total of 40 subjects will be divided into two groups. Group A- scaling and root planing followed by copper nanoparticles gel application in residual pockets, Group B - Scaling and root planing followed by Chlorhexidine gel application in residual pockets to assess the clinical outcomes in terms of Papillary Bleeding Index (PBI), Modified Plaque Index (PI), Probing Pocket Depth (PPD), Relative Attachment Level (RAL) at baseline, 1 month and 3 months as local drug delivery agent in patients with periodontitis. It will be made clear to the potential subjects that participation will be voluntary and written informed consent will be gained from those who accept to contribute.

Inclusion criteria

- Both males and female patients
- Age range between 35 -55 years
- Subjects should have at least 20 natural teeth.

- Patients diagnosed with Generalized Periodontitis Stage 2 Grade B currently stable without any risk factor (2017 World Workshop on the classification of periodontal and peri-implant diseases and conditions)
- Patients ready to give informed consent and ready to collaborate with the study protocol

Exclusion criteria:

- Pregnant/lactating mothers
- Smokers/tobacco in any form
- Patients who have undergone periodontal therapy, antibiotic or antiseptic therapy 6 months former to the study
- Patients with bleeding disorders or under immunosuppressive chemotherapy
- Any other systemic disease which can alter the course of periodontal disease

Data concerning their eating habits, oral hygiene habits, gingival and periodontal condition along with other standard clinical records will be documented in the specifically planned proforma. Subjects will be inspected in natural light with the help of mouth mirror, tweezers, the cotton balls and Williams graduated periodontal probe.

Clinical measurements -The clinical evaluation of the participants will be done by Papillary Bleeding Index (PBI) by Saxer and Muhlemann and Modified Plaque Index (MPI) by Turesky et al modification of Quigley-Hein Index, Probing pocket depth (PPD), and clinical attachment loss (CAL). PPD and CAL measurements will be achieved at six positions per tooth (mesial, middle, and distal points at the buccal and palatal aspects). CAL will be checked from the cemento-enamel junction to the base of the pocket. Clinical assessment of the parameters will be done at baseline, 1 and 3 months. All the measurements will be performed by a single calibrated examiner (SM).

- Design & development:** Carbopol 934 (1% w/v) will be weighed and soaked overnight in the distilled water at 4°C. Copper nanoparticles (0.005 % w/v) will be added to the carbopol solution and mixed thoroughly. Methyl paraben (0.18% w/v) and propyl paraben (0.02% w/v) will be added as preservative to the above dispersion. Finally 1N NaOH solution will be added drop wise to the above dispersion until it forms the gel. The obtained gel will be stored in the air tight containers in the refrigerator for further studies.
- b.

Facilities and Instrumentation required : Cone and plate Brookfield viscometer (CAP 2000+, Brookfield Engineering Laboratories, MA, USA) for viscosity measurement. MTT assay (cell viability) against mouse fibroblast, Time kill assay, Biocompatibility study with cell line to evaluate cytotoxicity, magnetic stirrer.

Consumables (Scientific materials): Agar plates, copper nanoparticles, Carbopol, Dulbecco's Modified Eagle Media (DMEM) with low glucose - (Gibco,Invitrogen),Fetal bovine serum (FBS) - (Gibco, Invitrogen), Antibiotic – Antimycotic 100X solution (Thermofisher Scientific), MTT staining.

Expected output and outcome - Copper nanoparticles gel is expected to exhibit antimicrobial property and decline of periodontal pocket depth and gain in clinical attachment levels in patients with periodontitis.

f. Industry/Institute Collaboration

- (i) Name of the Collaborating Industry/Institute- Dr. Kishore Bhat, Prof & Head of the Department of microbiology
- (ii) Collaboration Details- Maratha Mandal's NGH institute of Dental Sciences 7 Research centre,Belgaum,Karnataka-590010

(iii) Additional Details if any –ph no-0831-2477682 ,drkgbhat@yahoo.com

- g. **Funding required from I-STEM (with justification):** An effective in vivo analysis of copper nanoparticles gel in patients with periodontitis can be done to evaluate the anti-inflammatory as well as antimicrobial property. To date, there is no evidence of Cu nanoparticles gel antimicrobial efficacy and the safety of it in the dental infections and on the improvement of clinical parameters (reduction in periodontal pocket depth and gain in clinical attachment level) in patients with periodontitis.

Details of Requirements & Mode of the Engagement:

- (i) Short term Engagement: 6 months
- a. Usage of testing/characterization facilities across the country (Characterization Mode)
- i. Testing Charges: Rs. 70,000/-
 - ii. Consumable charges: Rs. 10,000-15,000
 - iii. Travel Cost (Boarding and Lodging, if any): Rs. 25,000-30,000.
- b. Usage of fabrication and testing facilities across the country (Fabrication Mode)
- i. Fabrication and testing Charges: Rs. 8000/-
 - ii. Consumable charges: Rs. 5000/-
 - iii. Travel Cost: Rs. 25,000-30,000.
- (ii) Medium term Engagement: NIL
- a. Execution of project in any one of the Host Institution (Project Mode)
- a. Fabrication and or testing Charges
 - b. Consumable charges (if any)
 - c. Travel Cost (Boarding and Lodging, if any)
- b. Execution of project in Multi Host Institutions (Project Mode)
- a. Fabrication and or testing Charges
 - b. Consumable charges (if any)
 - c. Travel Cost (Boarding and Lodging, if any)

(Round-trip to the Host Institution by 2nd class (Non-AC) railway via the nearest route)

Details of User's Bank Account: SAVING ACCOUNT

(Please send a copy of the cancelled cheque/copy of the passbook carrying all the information needed)

Beneficiary Name (User's name)- Dr.Swapna Mahale

PAN: ACCPM6620J

Bank Account No-.10338746767

Name of the Branch: State Bank Of India, Cidco Colony
Vilholi, Nashik

IFSC Code: SBIN0007235

Note: Proposed proposal must be executed within stipulated duration (max. 6 month) to avoid fund availability issues. Travel form will be provided by the I-STEM office. The users will submit the technical report, original invoice (duly signed by the Head of the Institution) raised by the Host Institution through I-STEM portal only along with a copy of the travel forms and original tickets through post to the Nodal Officer, I-STEM, Indian Institute of Science, Bangalore. A scan copy of all the documents may be sent in advance.