Bharath
INSTITUTE OF HIGHER EDUCATION AND RESEARCH
(Declared as Deemed-to-be University under section 3 of UGC Act, 1956)
(Vide Notification No. F.9-5/2000 - U.3, Ministry of Human Resource Development, Govt. of India, dated 4th July 2002)
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Chennai - 600 073. Tamil Nadu.

Ref. No.SMS-2018-O-10 Date: 06.02.2020

TO

Mr. S. Jai Kumar
Assoc.Professor/Pharmacology,
BIHER.

Thro: Concern Head of the Department

Greetings!!!

We are happy to announce that the Research Advisory Committee has approved your proposal for Seed Money Scheme-2018 which was presented by you. You are requested to complete the proposal and send the progress report to the Dean Research in the prescribed time period.

Title of the Project: Bacteriological Profile and Spectrum of Susceptibility Pattern in Diabetic Foot Ulcer Patients at Tertiary Care Hospital, Puducherry

Seed Money Amount: Rs.1, 00,000/- (Rupees One Lakh Only)

Approved on: 03.02.2020

Payment details:

Voucher No.65 **Dated: 12.02.2020**

With Regards

Dean-Research

Bharath University

SELAIYUR, CHENNAI - 600 073, TAMIL NADU, INDIA.

CASH / PAYMENT VOUCHER

Date 12/02/2020

V.No. 65

Debit _____ Amount

Rs. 1,00,000/-

PAID TO Dr. S. Jaikumar

RUPEES One lakh only

TOWARDS Seed Money Scheme - 2018

BHARATH UNIVERSITY CHENNAI 600 073. INDIA.

Authorised by **Finance Manager** **Cashier/Accountant** **Payee's Signature**

PROPOSAL SUBMISSION

1. **Details of Principal Investigator**

Name	: Dr. S. Jaikumar
Designation	: Assistant Professor
Highest Qualifications	: Ph.D.
Department	: Pharmacology
E-mail	: jaipharma2007@gmail.com
Contact no	: 8825343635
Date of Joining	: 17.08.2009

2. **Details of Co-Principal Investigator**

Name	: Dr. Somasundaram G
Designation	: Professor
Highest Qualifications	: MD
Department	: Pharmacology
E-mail	: somasundaramganesan8@gmail.com
Contact no	: 9677337050
Date of Joining	: 25.02.2016

Technical details

1. Introduction:

Diabetes mellitus is one of the major endocrine disorders of global concern. It is a serious health problem expanding worldwide where foot ulcers and lower extremity amputations are among the most serious complications associated with it [1]. Foot ulceration and infection in diabetic patients is one of the major causes of morbidity, hospitalization and foot amputation Hence there arises the need to evaluate these infecting microorganisms on a routine basis in addition to administering regular glycemic control, wound care, surgical debridement, pressure-off loading and maintaining adequate blood supply[2]. Once the protective layer of skin is broken, the deep tissues are exposed to bacterial colonization. Infections are facilitated by immunological deficits (especially in neutrophils), which are related to DM, and they rapidly progress to the deep tissues. Patients with DM frequently require minor or major amputations of the lower limbs (15–27%), and in more than 50% of cases, infection is the preponderant factor[3]. The life time risk to a person with diabetes for developing foot ulcer could be as high as 25% [4]. Infection may be caused by pathogenic bacteria originating from external environment as well as by bacteria forming physiological microflora of skin. The presence of infection depends mainly on the number of microorganisms residing in the wound, whereas the healing process depends on the type of bacterial strains and their pathogenicity[5].

2. Review of status of Research and Development in the subject

These infections are polymicrobial in nature. Escherichia coli, Proteus spp., Pseudomonas spp., Staphylococcus aureus and Enterococcus spp., are reported as frequent organism isolated from cases of diabetic foot infections [6]. The presence of MRSA and ESBL strains further worsen the prognosis and increase the risk of amputation [7]. Providing effective antimicrobial therapy plays a major role in treating these infections.

2.1. International Status:

Foot infections account for 20% of hospitalization of patients with DM annually. Infection worsens the wound infection, delays the healing mechanism and if interventions are not taken in time, it can progress to systemic infection, septicemia, amputation or even death. The vital components involved in treating diabetic foot infections are blood sugar control, treating co-morbidities, broad-spectrum antibiotic therapy, surgical treatment, proper dressing and wound care, personal hygiene, and prevention of recurrence.

2.2. National Status:

NIL

3. Progress/ achievement so far, if any

a). Reference papers was collected.
b). Literature survey was studied.
c). Materials and methods were designed.

4. Work plan

4.1 Methodology

The present study was conducted in the Department of Microbiology at Sri Lakshmi Narayana institute of medical sciences, Pondicherry during the period of June 2020 to August 2020. Sample collection: A total of 124 pus samples were collected from patients having foot ulcer infections, 26 samples from patients with ulcers who were non-diabetic formed control group admitted at surgery ward in Sri Lakshmi Narayana institute of medical sciences, Pondicherry. After obtaining proper patient informed consent samples collected from the patients. All swabs were collected before applying an antiseptic dressing to the wound and before starting treatment. Infected area should be decontaminated with 70% ethyl/ isopropyl alcohol. Wearing a sterile, disposable gloves samples (purulent drainage or curetted material) were collected from the deeper portion of the ulcers (ulcer base) by using 2 sterile swabs. The samples were collected by making a firm, rotatory movement with the swabs. Cultures are best taken from the ulcer base. Care was taken not to touch the adjacent skin margins to avoid contamination with the skin commensals/. One swab was used for Gram staining and the other was used for culture. Complete history of the patients was recorded which includes Age, Sex, Socio-economic status, Duration of ulceration, Treatment (if any) for Diabetes mellitus and duration of Diabetes mellitus. The ulcers were graded according to the Wagner's grade classification. Wagner Grading System

1. **Grade 1**: Superficial Diabetic Ulcer
2. **Grade 2**: Ulcer extension
Involves ligament, tendon, joint capsule or fascia No abscess or Osteomyelitis
3. **Grade 3**: Deep ulcer with abscess or Osteomyelitis
4. **Grade 4**: Gangrene to portion of forefoot
5. **Grade 5**: Extensive gangrene of foot

After collection samples were transported to the Microbiology department. Samples were processed as per standard CLSI guidelines. Isolation and Identification Samples were subjected to Gram stain to screen for presence of bacterial pathogen. Samples were inoculated on Blood agar, Macconkey agar and Nutrient agar. Isolates were identified and confirmed by biochemical reaction.

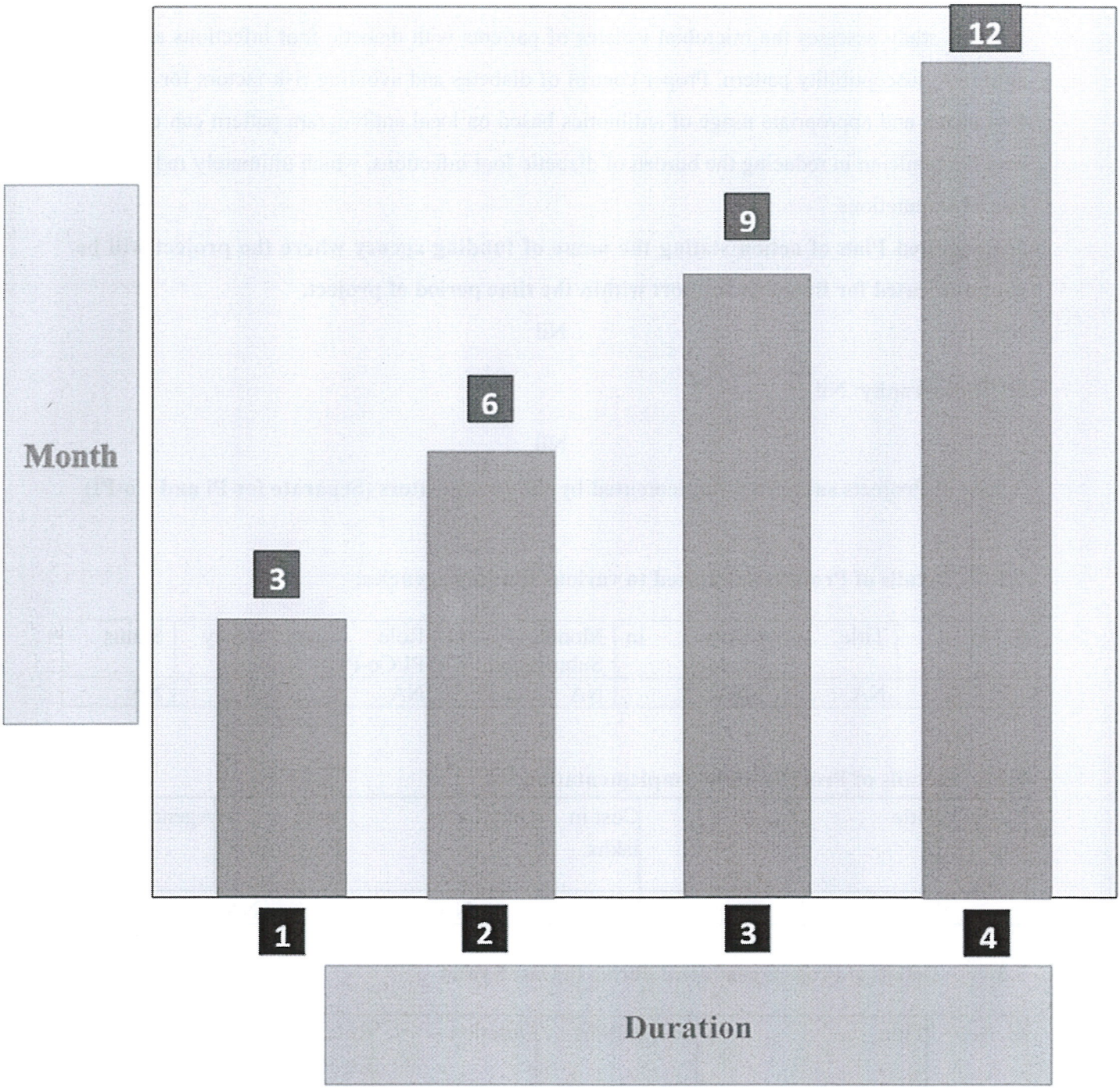
ANTIBIOTIC SUSCEPTIBILITY TESTING: The turbidity of the inoculated broth is compared with 0.5McFarland standard. Lawn culture of the broth suspension was made over the surface of the media and the antibiotic discs were placed and the plates were incubated at 37c for

24 hrs .The antibiotic susceptibility testing was done by the Kirby Bauer disc diffusion method, as per the CLSI guidelines.

GRAM NEGATIVE BACILLI: The antimicrobial discs which were used for GNB are Ampicillin (20µg), Aztreonam (30µg), Gentamicin (10µg), Amikacin (30µg), Cefazolin (30 µg), Cefuroxime (30µg) Ceftazidime (30µg), Cefotaxime (30µg), Ceftriaxone (30µg), Cefepime (30µg), Cefoperazone/sulbactam (75/10µg), Piperacillin/tazobactam(100/10µg), Imipenem (10µg), Meropenem (10 µg), Polymyxin B (300 units) and Colistin (10µg). GRAM POSITIVE COCCI Penicillin, Ampicillin, Azithromycin (15µg), Cefoxitin (30µg), Cefotaxime (30µg), Chloramphenicol (30µg), Clindamycin (2µg), Erythromycin (15µg), Oxacillin (1µg), Vancomycin (30µg), Teicoplanin (30µg)), Ciprofloxacin, Oxacilin (5µg), Linezolid (30µg) and Tetracycline (30µg) were used to study the susceptibility patterns of the Gram-positive cocci.

4.2 Time Schedule of activities giving milestones through BAR diagram. (Maximum of 1/2 pages)

S. No	Activity/ mile stolen	1st Year			
1	Literature review	**1-3 month**			
2	Analysis of existing work	-	**4-6 month**		
3	Designing & work initiated	-	-	**7-9 month**	
4	Statistics & Discussion with results	-	-	-	**10-12 month**


Month
3
6
9
12
1
2
3
4
Duration

4.3 Expected outcome within the time period of See Money Scheme

This study assesses the microbial isolates of patients with diabetic foot infections and their antibiotic susceptibility pattern. Proper control of diabetes and avoiding risk factors for diabetic foot ulcers and appropriate usage of antibiotics based on local antibiogram pattern can certainly help the clinician in reducing the burden of diabetic foot infections, which ultimately reduces the rate of amputations.

5. Suggested Plan of action stating the name of funding agency where the project will be communicated for financial support within the time period of project.

Nil

6. Bibliography: Nil

Nil

7. List of Projects submitted/implemented by the Investigators (Separate for Pi and Co-PI)

7.1 Details of Projects submitted to various funding agencies:

S. No	Title	Cost in Lakhs	Month of Submission	Role as PI/Co-PI	Agency	Status
	NA	NA	NA	NA	NA	NA

7.2 Details of Projects under implementation

Sl. No.	Title	Cost in lakhs	Duration	Role as PI/ Co-PI	Agency
	NA NA	NA	NA	NA	NA

7.3 Details of Projects completed during the last 5 years

Sl. No.	Title	Cost in lakhs	Duration	Role as PI/ Co-PI	Agency
	NA	NA NA	NA	NA	NA

8. List of publications published by the Investigators, if any:

a) Principal Investigator

S. No	Author names	Title of paper	Name of Journal	Vol (Issue)	Page no.	Year
1.	Abilash Sasidharannair Chandrakumari, Pammy Sinha, Shreelakshmidevi Singaravelu, and S **Jaikumar**	Prevalence of Anemia Among Adolescent Girls in a Rural Area of Tamil Nadu, India	J Family Med Prim Care	8(4)	1414–1417.	2019
2.	Asokan Balakrishnan Ramajayam1, **Jaikumar Sankarapillai2***, Somasundaram Ganesan2	Effect of ethanolic leaf extract of ipomoea sepiaria on sexual behaviour in male wistar albino rats	International Journal of Research in Pharmacology & Pharmacotherapeutics	7(1)	25-28	2018
3.	Somasundaram G1, Israel Raja Johnley I2, Sengottuvelu S3, **Jaikumar S1**	Effect of Pistia stratiotes Leaf Extract on Hepatic Functions against Paracetamol Induced Liver Damage in Rats	Scholars Academic Journal of Pharmacy	6(1)	1-3	2017
4.	Sridhar VR1, Jayakumar P2, Arun Seetharaman1, **Jaikumar S3***	Sedative effect of Lawsonia inermis root extract on phenobarbitone induced sleeping time in mice	European Journal of Molecular Biology and Biochemistry	3(3)	113-115	2016
5.	Sridhar VR1, Jayakumar P2, Arun Seetharaman1, **Jaikumar S3***	Influence of tabernae corymbosa root extract on Central nervous system mediated muscle Coordination in experimental animal	Acta Biomedica Scientia	3(4)	223-226	2016
6.	Sridhar VR1, Arun Seetharaman1 Jayakumar P2 and **Jaikumar S3***	Anticonvulsant Activiy Of Oleogum Resin Extract Of Commiphora Wightii Against	International Journal of Pharmacy & Therapeutics	7(2)	53-56	2016

		Pentylenetetrazole Induced Convulsion In Mice				

b). Co-Principal Investigator

S. No	Author names	Title of paper	Name of Journal	Vol (Issue)	Page no.	Year
1.	**Somasundaram G1,** Israel Raja Johnley I2, Sengottuvelu S3, **Jaikumar S1**	Effect of Pistia stratiotes Leaf Extract on Hepatic Functions against Paracetamol Induced Liver Damage in Rats	Scholars Academic Journal of Pharmacy	6(1)	1-3	2017
2.	Asokan BR1, Jaikumar S2*, **Somasundaram G2**	Anti-Diarrhoeal Activity of Ethanolic Leaf Extract of Luffa Acutangula against Castor Oil Induced Diarrhoea in Rats	Scholars Academic Journal of Biosciences	5(11)	809-811	2017

9. Budget

SI. No	Head	Amount (Rs.)
1	BP Apparatus, Stethoscopes, Body weight weighing machine, SPSS version 16 Chicago, IL, USA, ECG machine	45000
2	Consumables (gels bottles, cotton, sprit, testing charges, tools, etc.)	10000
3	Travel support for the purpose of research work.	10000
4	Contingency	25000
5	Others consumables	10000
	Total	**1,00,000**

*In case of any joint proposal for purchasing a same equipment, each of the associated PLs is also required to give separate budget (without any clubbing) to avoid any ambiguity, if all the associated projects are not awarded by committee.

10. Name of at least two subject experts from the Institute and one from the outside Institute with their contact details:

1. **Dr. B R Ashokan** Professor in Pharmacology, Aarupadi Veedu Medical College and Hospital, Puducherry **Mobile No**: 82485 60347 **E-mail id:** brashokan@gmail.com	2. **Dr. S. Sengottuvelu** Professor in Pharmacology Department, Nandha College of Pharmacy, Erode - 638052 **Mobile No**: 9994426689 **E-mail id:** sengt@rediffmail.com

CERTIFICATE FROM THE INVESTIGATOR

Project Title: Bacteriological Profile and Spectrum of Susceptibility Pattern in Diabetic Foot Ulcer Patients at Tertiary Care Hospital, Puducherry.

It is certified that

1. I do hereby agree to submit a complete proposal for financial support to the external funding agency within the time period of SMS-2018.
2. I undertake that spare time on equipment procured in the project will be made available to other users.
3. I agree to submit a certificate from Institutional Biosafety Committee, if the project involves the utilization of genetically engineered organisms. I also declare that while conducting experiments, the Biosafety Guidelines of Department of Biotechnology, Department of Health Research, GOI would be followed in to.
4. I agree to submit ethical clearance certificate from the concerned ethical committee, if the project involved field trails/experiments/exchange of specimens, human & animal materials etc.
5. I agree to abide by the terms and conditions of SMS-2018, BIHER, and Chennai.

Name and signature of Principal Investigator

Name and signature of Co-Principal Investigator

Date: 28.01.2020
Place: Pondicherry

Forwarded by Head of the Department

Signature of the Head

DEAN
SRI LAKSHMI NARAYANA INSTITUTE OF MEDICAL SCIENCES
OSUDU, AGARAM VILLAGE,
KOODAPAKKAM POST,
PUDUCHERRY - 605 502

PROJECT EVALUATION FORMAT

Recommendation sheet

Name of the Principal Investigator	Dr. S. Jaikumar
Name of the Co-Principal Investigator	Dr. Somasundaram G
Name of the Department	Pharmacology
Title of project	Bacteriological Profile and Spectrum of Susceptibility Pattern in Diabetic Foot Ulcer Patients at Tertiary Care Hospital, Puducherry
Recommendation of the evaluation committee (Recommended/Revision/Not Recommended)	RECOMMENDED
Financial allocation recommended	Rs. 1,00,000/-

SI. No.	Head	Amount
1	BP Apparatus, Stethoscopes, Body weight weighing machine, SPSS version 16 Chicago, IL, USA, ECG machine	45000
2	Consumables- Gel bottles, cotton, sprit, testing charges, tools, etc.	10000
3	Travel support for the purpose of research work.	10000
4	Contingency	25000
5	Other's consumables	10000
	Total	**1,00,000**

Name and Signature of the Research Advisory Committee members with date

Internal Quality Assurance Cell IQAC Pondicherry-0? *SLIMS*

(Dr. K. BALAGURUNATHAN)