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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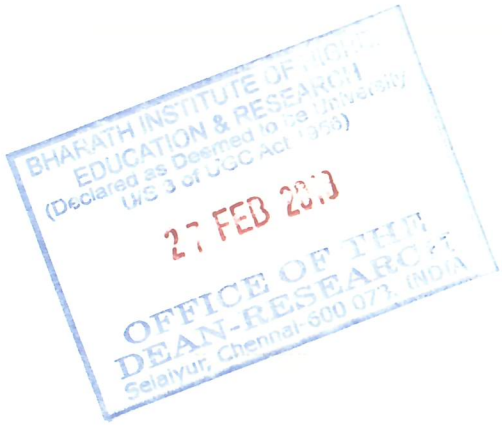
Ref. No.SMS-2015-O-06 Date: 27.02.2018

TO

Mr. E. Prabhakar Reddy
Professor/Biochemistry,
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-2015 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: Evaluation of Thyroid Hormone Levels Before and After Thyroidectomy

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

Approved on: 21.02.2018

Payment details:

Voucher No.41 **Dated: 02.03.2018**

With Regards

Dean-Research

Bharath University

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

CASH / PAYMENT VOUCHER

Date 02/03/2018

V.No. 41

Debit _____ Amount

Rs.

PAID TO Dr. E. Prabhakar Reddy

RUPEES One Lakh Only

TOWARDS Seed Money Scheme -2018

BHARATH UNIVERSITY CHENNAI 600 073. INDIA.

Authorised by **Finance Manager** **Cashier/Accountant** E. Prabhakar Reddy **Payee's Signature**

PROPOSAL SUBMISSION

1. **Details of Principal Investigator**

Name	: Dr. E. Prabhakar Reddy
Designation	: Professor
Highest Qualifications	: Ph.D.
Department	: Biochemistry
E-mail	: drpebyreddy@gmail.com
Contact no	: 9159186879
Date of Joining	: 21.10.2009

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

Name	**: Dr. A. Vaithiyalingam**
Designation	**: Professor**
Highest Qualifications	**: MD**
Department	**: Orthopedics**
E-mail	**: drvaithiyalingam@gmail.com**
Contact no	**: 9500077553**
Date of Joining	**: 26.10.2009**

Technical details

1. Introduction:

Thyroid-stimulating hormone (TSH) is synthesized and secreted by the anterior lobe of the pituitary gland. TSH acts on thyroid follicular epithelium and triiodothyronine (T3) and thyroxine (T4) hormones regulate the synthesis and release of TSH at the pituitary level and indirectly affect TSH production by their effect on TRH. These hormones act on diverse types of cells in human body and are involved in the maintenance of basic metabolism. TSH secretion is regulated by thyrotropin releasing hormone (TRH) secreted by hypothalamus. TSH belongs to a subset of the cysteine-knot growth factor super family. It is a heterodimer consisting of one alpha and one beta subunit associated by non-covalent bonds1. TSH is closely related to luteinizing hormone.

Thyroid hormone replacement therapy is required after the thyroid is completely removed surgically (i.e. total thyroidectomy). Studies have shown that thyroid hormone replacement is also needed ~40% of the time after a partial thyroidectomy (i.e. removal of one thyroid lobe). It is unclear what the contribution to the levothyroxine dose is by the remaining thyroid remnant after a partial thyroidectomy. The authors of this study compared thyroid hormone blood levels after thyroid surgery in patients with papillary thyroid cancer who had normal thyroid function before their surgery to that of controls matched by serum TSH concentration.

All patients considering thyroid surgery should be evaluated preoperatively with a thorough and comprehensive medical history and physical exam, including cardiopulmonary (heart) evaluation. Any patients who has had any change in voice or who have had a previous neck operation should have their vocal cord function evaluated preoperatively. Possible risks of thyroid surgery include: 1) bleeding that can cause acute breathing difficulty, 2) injury to the recurrent laryngeal nerve that can cause permanent hoarseness, and 3) damage to the parathyroid glands that control calcium levels in the body, causing hypoparathyroidism and hypocalcemia. The overall risk of complications should be <2% with an experienced surgeon.

Previous studies were reported2-5 compared postoperative T3 levels in patients on levothyroxine (LT4) therapy with their own preoperative levels or those in euthyroid controls. These studies indicate that in the athyreotic condition after the total thyroidectomy during LT4 therapy patients with normal serum thyrotropin (TSH) levels had mildly low serum free T3 (fT3) levels, and patients with suppressed serum TSH levels had normal serum fT3 levels. The question arises over which of these two patient groups is in a euthyroid condition. In humans, it is unclear whether such mild T3 defi ciency affects the thyroid hormone action in postoperative athyreotic patients on LT4 therapy. Based on this our study aim is to study patients who underwent total thyroidectomy before and after LT4 therapy in order to clarify whether a mild T3 defi ciency affects thyroid function in postoperative athyreotic patients on LT4 therapy and which should not have an impact on conversion of T4 to T3 by thyroid tissue6, were selected for the present study.

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

Anwar, A., & Dharmayanti, I. (2014). Pneumonia pada Anak Balita di Indonesia. Jurnal Kesehatan Masyarakat Nasional, 8(8), 359–365.

Thyroid hormone replacement (THR) therapy in athyreotic patients following thyroidectomy for thyroid cancer should be a relatively straightforward clinical problem to solve. The thyroid is absent, the hormone levels are low, the physician prescribes a dose of levothyroxine to replace what the body would otherwise manufacture, and that resolves the problem. Synthetic levothyroxine (L-T4) has been available since the 1960s, and despite its availability for 60 years physicians can be divided in their treatment of these patients.1 Standard of care is to titrate the L-T4 to suppress the serum thyroid-stimulating hormone (TSH) level, which is otherwise trophic for growth of normal as well as malignant thyroid cells.2–7 Nevertheless, as simple a clinical intervention as this seems, one of the most common dissatisfactions for athyreotic patients is the perception that the dose of thyroid hormone (TH) is incorrect, resulting in complaints of lethargy, weight gain, fatigue, and "brain fog."8,9 In fact some patients hesitate to have a thyroidectomy for thyroid cancer because of the widespread perception that all patients following surgery end up with the problems above. While most patients do well on THR with serum TSHs in the range of 0.01 to 0.3 mU/L, a proportion of patients requesting multiple referrals to endocrinologists or naturopathic practitioners are dissatisfied with their treatment. The aim of this paper is to review the basis for rational THR and to identify the main pitfalls encountered in patients following thyroidectomy for thyroid cancer.

2.1. International Status:

Hormone replacement after thyroid and parathyroid surgery is a common clinical challenge. The initiation of hormone replacement therapy is not always a simple matter, as it often overlaps with the transition from inpatient to outpatient care (i.e., from surgery and the immediate postoperative period to the period of ambulatory follow-up), and hormone replacement is either begun or continued by physicians from multiple specialties (surgery, internal medicine, family medicine). Permanent hypothyroidism arises not only after total or subtotal thyroidectomy, but also in 11% to 28% of patients that have undergone hemithyroidectomy. Risk factors for permanent hypothyroidism include seropositivity for TPO (thyroid peroxidase) antibodies, high normal preoperative TSH (thyroid stimulating hormone) levels, and histologically confirmed thyroiditis, but not age, sex, family history, or weight of the resected tissue. Patients who were in euthyroid status before they underwent elective surgery may need a change of their hormone dose afterward depending on the extent of the procedure, even if they are receiving replacement therapy that is closely adapted to body weight: this is true in 17% to 42% of cases (for hemithyroidectomy and subtotal thyroidectomy, respectively).

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

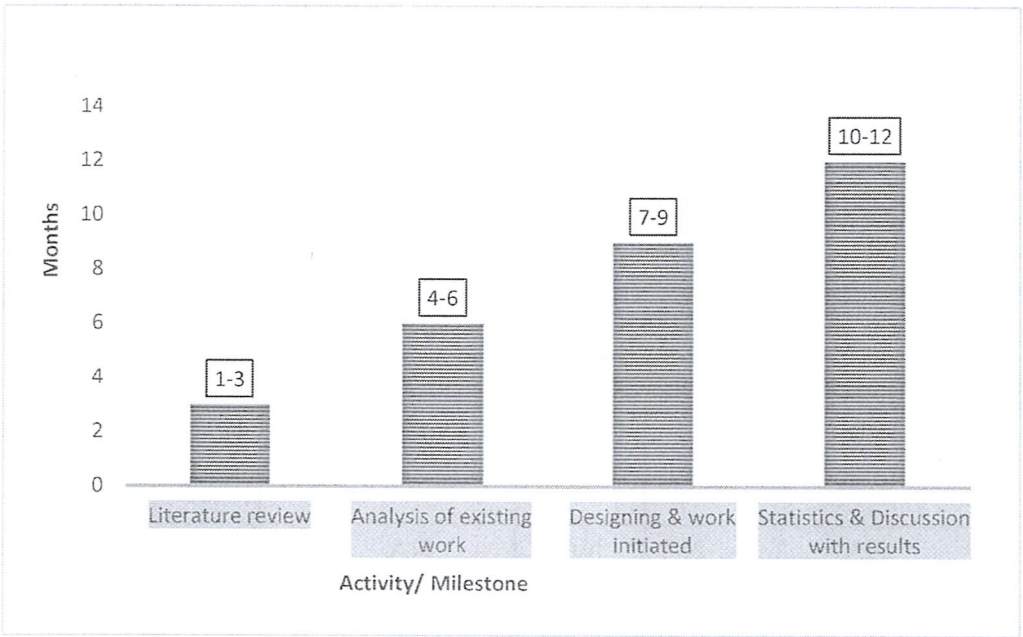
4.1 Methodology

Patients: This nonrandomized, controlled, prospective cohort study recruited euthyroid patients who underwent a total thyroidectomy for papillary thyroid carcinoma at Sri Lakshmi Narayana institute of medical sciences and Thanjavur medical college. Exclusion criteria were: (i) patients with thyroid malignancies other than papillary carcinoma; (ii) patients with thyroid dysfunction, such as Graves' disease, thyroid dyshormonogenesis, autonomously functioning thyroid nodules, or hypothyroidism; (iii) patients taking drugs known to affect thyroid function or thyroid hormone metabolism, such as a steroid, estrogen, amiodarone, lithium, b-blocker, sucralfate, iron, or iodine-containing drug; (iv) patients with chronic or serious diseases that affect lipid or bone metabolism such as cardiac, pulmonary, hepatic, renal, or pancreatic diseases, diabetes, or hyperparathyroidism; (v) patients taking a lipid-lowering agent during the study period; (vi) patients with a serum triglyceride level >400mg/dL; (vii) patients taking drugs known to affect bone metabolism, such as a calcium supplements, vitamin D, calcitriol, dihydrotachysterol, or bisphosphonates; (viii) pregnant, lactating, or perimenopausal patients; (ix) patients with abodymass index (BMI) <18 or >30kg/m; and (x) patients with a physical disability or participating in a competitive sport. Patients who had postsurgical hypoparathyroidism, those who had developed metastasis, and those who failed to achieve the target TSH levels were also excluded. The present study was approved by the Ethics Committee and taken patient informed consent in the study.

This study included 65 patients (22–60 years old) who underwent a total thyroidectomy for papillary thyroid carcinoma. All patients also underwent central node and/or modifi ed neck dissection. An attempt was made to preserve parathyroid glands in situ with their blood supply. However, if they were resected or devascularized, they were minced and autotransplanted into the sternocleidomastoid muscle. The patients were initially administered 2.0lg/kg of LT4 daily after the total thyroidectomy. Thyroid function tests were performed one month after surgery. The target serum TSH levels were strongly suppressed TSH levels for the 40 high-risk patients, mildly suppressed TSH levels for the 25 intermediate-risk patients.

4.2 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**



4.3 Expected outcome within the time period of See Money Scheme

This study concludes patients with a thyroid remnant after a partial thyroidectomy have higher T3 levels than patients who have undergone a total thyroidectomy. Our results are that remaining thyroid remnant after a partial thyroidectomy continues to contribute to the maintenance of serum free T3 levels even if the patient is on levothyroxine. The clinical significance of these results is not known. There are some possible limitations; first, the limited number of study patients, unequal group distribution, and single time point reduced the internal validity of the study. Second, the follow-up period was not long enough to investigate the effect of the difference in postoperative T4 treatment on the endpoint of metabolic disorders such as atherogenesis, BMD, or bone fracture. Further well designed studies are necessary to clarify the long-term effect at multiple centers

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
1	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
1	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
1	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
	S. V. Rama RaoA,B, M. V. L. N. RajuA, B. PrakashA, U. RajkumarA and **E. P. K. ReddyA**	Effect of supplementing moringa (*Moringa oleifera*) leaf meal and pomegranate (*Punica granatum*) peel meal on performance, carcass attributes, immune and antioxidant responses in broiler chickens	Animal Production Science	8(5)	1-7	2018
1.	Kalpana Thalaval, ***E Prabhakar Reddy2**, and A Vaithilingam3.	HCG and CA-125 Levels In Pregnancy And Abortion Patients.	Research Journal of Pharmaceutical, Biological and Chemical Sciences	8(2)	2745-2749	2017
2.	1B. Sai Ravi Kiran*, 2T. Mohana Lakshmi, 3R. Srikumar, **4E. Prabhakar Reddy**	Total Antioxidant Status and Oxidative Stress in Diabetes Mellitus and Metabolic Syndrome	International Journal of Pharmaceutical Sciences Review and Research	40(1)	271-277	2016
3.	V Kowsalya, R Vijayakumar, R Chidambaram, R Srikumar, **E Prabhakar Reddy,** S Latha, I Gayathri Fathima, C Kishor Kumar	A study on knowledge, attitude and practice regarding voluntary blood donation among medical students in Puducherry, India.	Pakistan Journal of Biological Sciences	16(9)	439-442	2013

9. Budget

SI. No	Head	Amount (Rs.)
1	BP Apparatus, Stethoscopes, Body weight weighing machine, SPSS version 16 Chicago, IL, USA, ECG machine	50,000/-
2	Consumables (gels bottles, cotton, sprit, testing charges, tools, etc.)	25,000/-
3	Travel support for the purpose of research work.	10,000/-
4	Contingency	10,000/-
5	Others consumables	5,000/-
	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. Seshadri Reddy** Assistant Professor, Dept of Biochemistry AIIMS Deoghar **Mobile No**: 8106145001 **E-mail id:** lifeschemistry@live.com	2. **Dr. Manne Munikumar** Data Manager (Bioinformatics) Clinical Division, ICMR-National Institute of Nutrition Jamai-Osmania (Post) Hyderabad-500007, Telangana **Mobile No**: 9492373997 **E-mail id:** mannemk@gmail.com

CERTIFICATE FROM THE INVESTIGATOR

Project Title: Evaluation of Thyroid Hormone Levels Before and After Thyroidectomy

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: 03.01.2018
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. E. Prabhakar Reddy
Name of the Co-Principal Investigator	Dr. A. Vaithiyalingam
Name of the Department	Biochemistry
Title of project	Evaluation of Thyroid Hormone Levels Before and After Thyroidectomy
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	50,000/-
2	Consumables- Gel bottles, cotton, sprit, testing charges, tools, etc.	25,000/-
3	Travel support for the purpose of research work.	10,000/-
4	Contingency	10,000/-
5	Others consumables	5,000/-
	Total	**1, 00, 000/-**

Name and Signature of the Research Advisory Committee members with date.

Internal Quality Assurance Cell * IQAC * Pondicherry-02 * SLIMS *

(Dr. A. Suguna)