Govt. of Karnataka

BANGALORE MEDICAL COLLEGE & RESEARCH INSTITUTE

[An Autonomous Institute of Govt. of Karnataka]
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No. BMCRI/Project/07/2021-22

Office of the Director cum Dean
Bangalore, Dated: /11/2021
01/11/2021

RENOTIFICATION

Sub: Inviting quotation for Coverage Insurance to Clinical trial participants under the Ministry of Ayush funded Covid-19-Ayush Research In collaboration with NIMHANS, Bengaluru.

Sealed quotations are invited to quote the competitive rates for the Coverage Insurance to Clinical trial participants under the Ministry of Ayush funded COvid-19-Ayush Research In collaboration with NIMHANS, Bengaluru on or before 10/ 12/2021. (Details attached in Annexure).

1. Quoted price

(a) The tenderer may quote for the item in the format of quotation attached;
(b) All duties, taxes and other levies payable by the tenderer (including all taxes on the finished goods) shall be included in the item rate.
(c) The rates quoted for the item shall be fixed for the duration of the contract and shall not be subject to any adjustment.
(d) Rates for supply of partial quantity of the item is not acceptable.
(e) Corrections if any shall be made by crossing out, initialing, dating and rewriting.
(f) Cable or Facsimile quotations are not acceptable.

2. a) Each tenderer must submit only one quotation
b) Tenderers should have registered with appropriate authority.
c) Should have register number for GST.

3. Validity of quotations:

The quotation shall remain valid for a period not less than 30 days after the deadline fixed for Submission of quotations.

4. Evaluation of quotations:

The Purchaser will evaluate and compare the quotations determined to be substantially responsive i.e., which are properly signed, and conform to the terms and conditions and specifications in the Following manner:

(a) The evaluation will be done including the Sales tax. If the tenderer has not included the Sales tax in his quotation for the item rate, and has also not indicated the rate of Sales tax applicable, the quoted rate will treated as though it is inclusive of the Sales tax and no extra payment for Sales tax will be made;

(b) The evaluation would be done for the item separately The tenderer who has quoted for partial quantity of the item would be treated as non-responsive. Purchaser will award the contract for the item separately to the lowest responsive tenderer for the item.

5. **Last date and time of receipt of quotations:**
You are requested to submit the sealed quotations superscribed on the envelope as **"Coverage Insurance to Clinical trial participants under the Ministry of Ayush funded COvid-19-Ayush Research In collaboration with NIMHANS, Bengaluru. Due on 10/12/2021" before 5:30PM.** We look forward to receiving your quotations.

Director cum Dean
Bangalore Medical College and
Research Institute, Bangalore.

Copy to:

1. PA to Director cum Dean, BMCRI requesting to publish in website.
2. Dr.Kishore Kumar.R Co-Principal Investigator, Ayush Research Project
3. Notice Board.
4. To all the Registered Vendors through E-mail

CLINICAL TRIAL PROPOSAL FORM FOR INSURANCE

1. **Name of Insured** – Subjects/participants of the clinical trial.
2. **Institution: Bangalore Medical College and Research Institute Bangalore**
3. **Title of the Project**: An open Label Controlled Clinical Study to evaluate the efficacy of Ayurvedic Medicines Tab. Sudarshana churna, tab. Yastimadhu and Amritharista as add-on therapy to standard of care on symptomatology, inflammatory markers and RT-PCR in COVID-19 (mild to moderate) positive patients.
4. **Name of drug being tested** – Tab. Sudarshana churna, tab. Yastimadhu and Amritharista.
5. **Category of the drugs:** Ayurveda Drugs quoted in Ayurvedic Pharmacopeia and Approved by Govt. of India in General Practice in other viral fevers
6. **Has approval been obtained from the MCC and Ethics Committee**: Yes approval obtained from Ethics Committee - Bangalore Medical College and Research Institute, Bengaluru.
7. **Cover required**:
    a. **Limit of Liability required**: 40,000,00/-
    b. **Per Subject Limit required:** 5,00,000/-
    c. **No. of Subjects: 52**

8. Describe the intended purpose of the product and how it will be used when approved:

The intended purpose of the drugs is to evaluate the add on effect of Ayurvedic formulation in positive cases of COVID – 19 to enable further applications ongoing battle against COVID-19.

9. Phase of testing currently underway or expected within the next 12 months:

The drugs are mentioned in Ayurveda treatises for management of pandemic conditions similar to COVID – 19. They are time tested and regularly used in clinical practice by Ayurvedic physicians.

10. Describe the nature and purpose of the study

The study is a Controlled clinical study to evaluate the add on effect of Ayurvedic formulation on patients diagnosed with COVID – 19. The purpose of the study is to enable these Ayurvedic formulations for their further applications in the ongoing battle against COVID-19.

11. How are the drugs administered?

The drugs are administered orally along with luke warm water.

12. What part of the body or body system will be affected?

The drugs will act as antiviral systemically.

13. What are the possible or known side effects or complications?

There are no possible or known Adverse effects reported till date on these Ayurvedic formulations.

14. What harm might occur if the product did not work as intended?

The Ayurvedic formulations will not cause any harm if they do not work as intended. It will be at the most ineffective against COVID-19 virus and no drug interactions have been reported with Modern medicines that are given as standard of care.

15. Total number of participants in the trial (currently underway or expected within the next12 months; including control group:

Total 52 participants (26 in control group and 26 in trial group)

16. Characteristics of participants population (age, gender, physical condition)"

The participants selected for the study will be aged between 18 to 60 years; both male and female participants will be selected. Participants suffering from COVID – 19 devoid of Hepatic Dysfunction, Diabetes Mellitus, Renal Dysfunction, Pulmonary Dysfunction, malignancy, tuberculosis, neurological deficits, cardiovascular diseases, Hypertension, Psychiatric diseases and Pregnant / Lactating women will be excluded from the study.

17. Do you comply with all recommendations as set forth in the "Guidelines for good practice in the conduct of clinical trial in human participants" as issued by the Department of health?

YES

18. **Expected length of trial**: Six months.

19. Who will administer the testing? If not the applicant, please identify who and detail any Hold harmless/ Indemnification Agreements:

Senior Research fellow will administer the testing under the supervision of the investigators

20. Who will be the principal investigators in the trial? please identify who and detail any Hold harmless/ Indemnification Agreements:

a. Principal Investigator: Dr. Shashi Bhushan, B.L. MBBS, MD, FCCP (USA) Professor, Department of Pulmonary Medicine, Bangalore Medical College and Research Institute (BMC&RI), Bengaluru.

b. Co-Principal Investigator: Dr. Kishore Kumar R. MD (Ay.), Ph.D (NIMHANS) Professor of Ayurveda, Department of Integrative Medicine, National Institute of Mental health and Neurosciences (NIMHANS) Bengaluru

21. Where will the trial be Trial be conducted?

The trial will be conducted at Victoria Hospital, Bangalore Medical College and Research Institute, Bengaluru.

22. Briefly describe previous testing on the product including toxicity studies and explain any problems of adverse reactions which occurred:

The safety of these drugs has been established and listed in the Ayurvedic Pharmacopeia of India and Ayurvedic Formulary of India. There are in use by the Ayurveda practitioners all over the country for other known viral infections. According to Drugs and Cosmetics Rules 1945, Ayurveda, siddha and Unani drugs, given in 158 B as referred in 3(a) do not require safety studies. The Ayurvedic formulations are time tested, prescribed by Ayurveda physicians in their routine clinical practice and till date there are no reports on problems or adverse reactions on these formulations.

23. Describe any losses including reserves/ payments incurred during previous testing:

Not applicable

24. Has the product been used in other applications? Explain:

Yes, these Ayurvedic formulations are indicated and used to treat fever, cold and cough of varied pathology in Ayurvedic treatises and by Ayurvedic practitioners.

25. Copies of the following documents are available with the Investigators that will be provided once the quote is approved

- Protocol
- Consent form
- BMC& RI Ethics Approval letter

Contact Details (Please send information to both the email ids)

a. Principal Investigator: Dr. Shashi Bhushan, B.L. MBBS, MD, FCCP (USA) Professor, Department of Pulmonary Medicine, Bangalore Medical College and Research Institute (BMC&RI), Bengaluru. Mobile: 9448239644; Email: shashibhushanbmcri@gmail.com

b. Co-Principal Investigator: Dr. Kishore Kumar R. MD (Ay.), Ph.D (NIMHANS) Assistant Professor of Ayurveda, Department of Integrative Medicine, National Institute of Mental health and Neurosciences (NIMHANS) Bengaluru: Mob: 9845829174· Email: ayurkishore@yahoo.com