

Randomised controlled trial of RNB culminates successfully

CORRESPONDENT ■ ETAWAH

The randomised controlled trial (RCT) conducted at UPUMS, Saifai, to evaluate the safety and efficacy of world's first 'Allovedic' medicine Raj Nirwan Bati (RNB) in the treatment of mild to severe symptomatic Covid-19 patients has culminated successfully with encouraging results. This was conveyed by Dr Prof Raj Kumar, Vice-Chancellor, Uttar Pradesh University of Medical Sciences (UPUMS), Saifai. This landmark randomised control trial considered highest in the hierarchy of scientific evidence methodology is the result of a series of meticulously planned scientific studies and trials conducted at the University in the past few months during this Covid era. Dr Raj Kumar said that a pilot study-cum-single-arm clinical trial was conceptualised and successfully conducted in June/July at dedicated Covid hospital, UPUMS. Due registration for the same had been done at the apex body for the purpose- Clinical Trial Registry of India (CTRI). The study was approved by University's empowered corona committee, scientific and ethical committees. Three research articles incorporating the findings and results of this single-arm clinical trial, demonstrating the safety and efficacy of RNB in mild to severe symptomatic Covid-19 patients have been published in reputed national and international journals and have also been described in detail in the book 'Covidology-Sciences, Infrastructure & Management' published by UPUMS recently. Buoyed up by the encouraging results of this successful single-arm clinical trial, a double-blind randomised controlled trial was subsequently conducted in mild to severe symptomatic Covid-19 patients being treated at dedicated Covid Hospital at UPUMS, Saifai, during the months of June/July. Due registration for the same was also done at the apex body for the purpose- CTRI and approval was taken from the University's empowered corona committee, scientific and ethical committees. This trial was designed diligently as per contemporary allopathic medicinal research practices and guidelines. In this RCT 60 Covid-19 patients above 18 years with mild, moderate and severe symptoms were registered. Critically ill cases were not included in the study since



RNB is available only in tablet form presently and not in an injectable form. These 60 patients were distributed among two study groups. Thirty patients in the 'RNB Intervention group' received RNB medication whereas 30 patients in the 'Placebo Control group' did not receive RNB. All patients in both the study groups received concomitant treatment with hydroxychloroquine, antibiotics, anticoagulants, steroids and vitamins etc. as per standard established treatment protocols. In the RNB interventional group, 60 per cent (pc) of patients had co-morbidities like diabetes, hypertension, coronary artery diseases (CAD), hypothyroidism, bronchial asthma, COPD, oral carcinoma and head injury while in placebo control group only 23 pc of the patients had co-morbidities. Despite this fact patients in the RNB interventional group showed comprehensive improvement in their health status. Statistically significant findings of this RCT (with globally acceptable power of study) are as under: In the RNB intervention group 97 pc of patients on day 6 and all the patients on day 12, became RT-PCR negative. Whereas in the placebo group, 73 per cent of patients on day 6 and 90 pc of patients on day 12 became RT-PCR negative. Symptomatic improvement in the patients was assessed on the basis of mean days taken for relief of eight symptoms namely fever, cough, sore throat, breathlessness, chest tightness, fatigue, myalgia and taste sensation. The patients in RNB intervention group got relief in all the above symptoms in lesser days (mean 5.9 days) as compared to patients in placebo group (mean 7.1 days) and this was statistically significant. Besides considerable improvement in the chest X-ray findings was observed in 89 pc of patients during the course of treatment in RNB group. Whereas only 57.0 pc of the patients in placebo group showed improve-

ment. The mean platelet count of the patients in RNB intervention group increased significantly as compared to the placebo control group in the study period. The rate of increase in platelet count from the index value was 43 pc on day 6 and 80 pc on day 12 in the RNB interventional group compared to an increase of 28 per cent on day 6 and 75 pc on day 12 in the placebo control group. Mean values of various hematological or biochemical parameters namely haemoglobin, polymorphs, lymphocytes, urea, creatinine, bilirubin, many liver enzymes, international normalised ratio (INR), serum protein levels etc either remained within normal limits or changed non-significantly. This indicates that RNB does not have any adverse effect on liver, kidney, blood etc and has an excellent drug safety profile. The findings and results of this successful landmark RCT as well as the pilot study-cum-single-arm clinical trial, demonstrating the safety and efficacy of RNB in mild, moderate and severe symptomatic Covid-19 patients, have been sent to ICMR and CCRAS, Ministry of AYUSH, to strengthen fight against this pandemic. RNB can prove instrumental in containing the spread of this virus, treating Covid-19 patients and saving millions of lives. It is still an ongoing race against time to find a cure for this deadly virus. The scientific temperaments at UPUMS Saifai under the leadership of the V-C Dr Raj Kumar were ignited well in advance even before corona could knock at our doors. More than 25 research publications have been published during this period contributing significantly to the global scientific community. In-depth analysis of the mortality around the world illustrated the tissues and organ systems targeted ruthlessly by Coronavirus. A meticulously dedicated approach unearthed those components of our ancient medicinal system which have a proven scientific track record of strengthening and fortifying those susceptible organ systems. This paved the way for this novel herbo mineral formulation. RNB has been tested on all scientific principles of modern medicine (along with the scientific proof of each constituent), that is why it has been termed as world's first 'Allovedic' preparation despite the fact that it contains 11 established constituents of Ayurveda.