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# THE TIMES OF INDIA

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Taliban have denied that one of their top leaders, **Mullah Abdul Ghani Baradar,** has been killed in a shootout with rivals, following rumours of a split in the group

# CDRI achieves breakthrough in trial of Umifenovir in Covid-19 treatment

## 'Viral Load Turns To Zero If Proper Doses Are Given For 5 Days'

**Mohita.Tewari**@timesgroup.com

**Lucknow:** The Central Drug Research Institute (CDRI) on Tuesday claimed that the clinical trials of antiviral drug, Umifenovir, in treatment of Covid-19 have been successful.

The trial of Umifenovir on 132 Covid-19 patients showed that, if proper dose is given twice daily for five days, the drug can effectively reduce viral load to zero in mild or moderate symptomatic and asymptomatic patients by checking multiplication of the virus.

CDRI conducted phase-III trial on 132 coronavirus patients

Titled 'Phase III, randomized, double-blind, placebo controlled trial of efficacy, safety and tolerability of antiviral drug Umifenovir vs standard care of therapy in non-severe Covid-19 patients', the clinical trial was conducted at three institutions – KGMU, Ram Manohar Lohia Institute of Medical Sciences (RMLIMS) and Era's Lucknow Medical College and Hospital (ELMCH).

"Since Umifenovir is a broad spectrum antiviral and is being used as a safe over-the-counter drug for influenza and pneumonia for over 20 years in Russia, China and other countries, the first two trials were not mandatory," CDRI director Prof Tapas Kundu said.

▶**Inhibits virus entry, P 2**

# 'Umifenovir stops entry of virus into human cells'

## STRENGTHENING COVID COMBAT

- **CDRI** is the first institute in the world to plan Umifenovir dosage for **Covid-19** patients. It has also initiated the process for patent
- The viral load of mild/ asymptomatic **Covid-19** patients came to zero in **5 days** after being given **2 daily** doses of Umifenovir **800mg**
- The drug is **50-54%** economical as compared to other medications and safe for pregnant women & children
- **CDRI** plans to provide Umifenovir in the form of a syrup and puff inhalers

▶**Continued from P 1**

CDRI, therefore, directly went for phase-III trial, conducted on 132 patients either admitted in hospital or in home quarantine under the supervision of these hospitals," CDRI director Prof Tapas Kundu said.

"In a study, double-blind mode improves reliability of results by preventing bias when doctors evaluate patient outcomes. The results showed that viral load in mild, moderate or asymptomatic patients after being given two doses of Umifenovir (800mg) twice a day became zero in an average of five days. Patients did not experience any side-effects and their symptoms also did not turn severe," he said.

"Studies by CDRI in collaboration with CSIR-IMT, Chandigarh, also showed that Umifenovir exhibits good cell culture inhibition of SARS-Cov2, which suggests that the drug inhibits the entry of SARS-Cov2 virus into human cells," Prof Kundu said.

He said the institute was getting the dosage plan patented as it had not been used earlier for Covid-19.

"The Drug Controller General of India (DCGI) has evaluated the clinical trials report and in view of the highly encouraging results, he has asked the team to continue the studies on more mild, asymptomatic patients for grant of emergency approval of the drug," he added.

CDRI chief scientist Prof R Ravishankar, who led the team, said: "Umifenovir will be economical for treating Covid-19 patients as it is around 54% cheaper compared to current medication. Experts from the three hospitals said the drug is safe for pregnant women and children. We are looking into the possibility of Umifenovir syrup for children and also in powder form for puff inhalers."

According to CDRI, the head of KGMU's medicine department Dr Virendra Atam and medical superintendent Dr Himanshu Reddy, who were principal investigators, mentioned in their report that faster recovery of coronavirus patients would reduce virus shedding and consequent spread of infection to others.

It also said that the principal of Era's Medical College Prof MMA Faridi mentioned in his report that Umifenovir could be prescribed to pregnant women and children if approved by authorities.

Prof Vikram Singh from RMLIMS suggested that as Umifenovir was safe, it had significant efficacy on mild and asymptomatic patients and could also be useful as a prophylactic for high-risk patients.

CDRI spokesperson Sanjeev Yadav said, "Umifenovir was selected from 16 drugs suggested by CSIR after looking into the feasibility of synthesis using locally available chemicals at the peak of the pandemic. DCGI then gave permission for trials in June last year."

A team of CDRI chemists Ajay K Srivastava, Chandra Bhushan Tripathi, Nayan Ghosh and Nilanjana Majumdar and their students synthesized the drug and developed the process technology – chemical processing used to refine raw material into finished product – in record time.

The technology was then transferred to a Goa-based private pharmaceutical company within a month's time to make the "active pharmaceutical ingredient" and tablets for trials.

Finally, after securing ethical approvals and completing stability studies, the team took consent of patients and roped them in for the study.

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# Influenza drug found effective in tackling mild Covid-19: CDRI

**HT Correspondents**
letters@htlive.com

**LUCKNOW:** Umifenovir, an influenza drug popular in Russia and China, has been found effective in the management of Covid-19 cases, a recent study of the Lucknow-based Central Drug Research Institute (CDRI), has found.

CDRI, a Council of Scientific and Industrial Research (CSIR) institute under the ministry of science and technology, found the drug helpful in treating people with mild symptoms and has sought approval of the Drug Controller General of India (DGCI) to permit the sale of the drug.

Confirming the development CDRI director Prof Tapas Kundu said, "We have successfully completed Phase III, trial of efficacy, safety and tolerability of antiviral drug Umifenovir when compared with standard care of therapy in non-severe Covid-19 patients."

The director said that Umifenovir (Arbidol) was selected from among 16 drugs suggested for trial upon looking into the feasibility of synthesis using locally available chemicals during the peak of the first wave of the pandemic in May last year.

**CSIR-CDRI IS ALSO CARRYING OUT WHOLE GENOME ANALYSIS OF VIRUS STRAINS FROM SEVERAL HUNDRED PATIENTS AS REQUESTED BY THE STATE GOVT**

Ram Manohar Lohia Institute of Medical Sciences (RMLIMS). The trials were held between October 2020 and April 2021 after securing ethical approvals and completing the stability studies of the drug at CDRI. The scientists decided on a simple dose regimen of 800 mg two times a day for a maximum of 14 days.

"Umifenovir was found to inhibit the entry of the Sars-CoV-2 virus (causing Covid-19) into human cells. The team has completed an independent audit of the clinical trial data and statistical analysis as per the approved DCGI protocol which shows that Umifenovir is very promising in mild-asymptomatic Covid-19 patients," said the director. "The DGCI has also evaluated the clinical trials report and in view of the highly encouraging results, has asked the team to continue studies on more mild-asymptomatic patients for granting emergency approval of the drug," he added.

Prof R Ravishankar, who coordinated the team, said that Umifenovir is a broad spectrum antiviral used as a safe over-the-counter drug for influenza and pneumonia for over 20 years in Russia, China and other countries.

A team of chemists from CDRI including doctors Ajay K Srivastava, Chandra Bhushan Tripathi, Nayan Ghosh and Nilanjana Majumdar synthesised Umifenovir using locally sourced raw material and transferred the technology to Medizest, a Goa-based drug manufacturing firm to make tablets for the trial.

The DCGI, in June last year, cleared Phase III trials on asymptomatic, mild and moderate Covid-19 patients in King George's Medical University (KGMU), Era's Lucknow Medical College and Hospital, and

CSIR-CDRI is also carrying out whole genome analysis of virus strains from several hundred patients as requested by the state government.

These studies are being used to analyse the spread of various Covid-19 virus strains in UP. Keeping in mind the emerging viral infections, CDRI has established a 'Unit of Excellence in Virus Research and Therapeutics' in collaboration with the Dr APJ Abdul Kalam Technical University (AKTU) and KGMU on the initiative of chief minister Yogi Adityanath.