Efficacy of Favipiravir in treatment of mild & moderateCOVID-19 infection in Nepal: a multi-center, randomized, open-labelled, phase III clinical trial

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Abstract (300 word limit)

Problem Statement: The pandemic of COVID-19 has been a global public health emergency, with not a single antiviral drug being approved for treatment so far, except for Remdesivir. We sought to evaluate the efficacy of repurposed use of Favipiravir in the clinical outcomes of mild and moderate COVID-19 cases in Nepal.

Methods: We conducted a multicenter, randomized (1:1), open labeled, phase III clinical trial among adults diagnosed with mild to moderate COVID-19 infections, as an inpatient or outpatient basis. Patients with mild symptoms were randomly assigned to receive Favipiravir (study regimen: oral form, 1800 mg twice on Day1 and then 800mg twice daily for 5 days) or matching placebo. Those with moderate symptoms were randomly allocated to receive either Favipiravir (study regimen for 10 days) or intravenous Remdesivir (200mg on Day 1, followed by 100mg once daily for 5days). The primary outcome was to evaluate for clinical improvement among both the cohorts based on treatment received.

Here, we report an interim safety and efficacy analysis of the study.

Results: Between January 2021 to March 2021, a total of 90 cases (Mild: 70, Moderate: 20) with 61% being male, were enrolled from 8 different centers.
The result of analysis on clinical efficacy has been as reported in the table submitted herewith.

There was one minor event of increment in uric acid level and two events of elevated liver enzymes observed, however none of the adverse events required any hospital admissions or special intervention.

Conclusion: We conclude that Favipiravir has an excellent safety profile but we need to achieve a bigger sample size in order to evaluate for any possible efficacy in treatment of mild & moderate COVID-19 cases.

Image

Table1. Association between Favipiravir and clinical outcome (mild cases)

Clinical Outcome	Overall , n (%) (n=70)	Intervention group, n (%)		P-value
		Favipiravir(n=38)	Placebe(n=32)	
Clinical Improvement	57 (81.4)	30 (78.9)	27 (84.4)	0.785
Failure of Treatment	13 (18.6)	8 (21.1)	5 (15.6)	

Table2. Association between Intervention and clinical outcome (moderate cases)

Intervention result	Overall, n (%) (n=20)	Intervention group, n (%)		P-value
		Favipiravir(n=11)	Remdesivir(n=9)	
Clinical Improvement	17 (85.0)	9 (81.8)	8 (88.9)	1
Failure of Treatment	3 (15.0)	2 (18.2)	1 (11.1)	

Recent Publications (minimum 5)

1. Tubercular meningitis presenting as cerebral salt wasting syndrome in an adult : a case report (Annals of Medicine & Surgery ; Nov 2020)

2. Role of Statins in the Primary Prevention of Atherosclerotic Cardiovascular Disease and Mortality in the Population With Mean Cholesterol in the Near-Optimal to the Borderline High Range: A Systematic Review and Meta-Analysis (Hindawi, Advances in Preventive Medicine, 2020)

3. Staphylococcal toxic shock syndrome in a lactating mother with breast abscess : A case report (Annals of Medicine & Surgery; July 2020

4. A fixed-dose combination of Ledipasvir & Sofosbuvir +/- Ribavirin for treatment of Hepatitis C infection : a systematic review & meta-analysis (Drugs & Therapy Perspectives ; May 2017) 33, 348-360 (2017)

5. Neutrophil to lymphocyte ratio predicts short and long term mortality following revascularization therapy for ST elevation myocardial infarction (Cardiol J. 2014 Mar 27)



Biography (150 word limit)

Dr .Prabhat Adhikari, MD

Prabhat Adhikari, MD is an internal medicine, infectious disease and critical care physician who has been practicing in both Nepal and the USA. Besides his clinical practice, Dr Adhikari has been leading some research projects in Nepal, mostly in the field of Infectious Diseases & ICU. He has special interest in AMR, TB, COVID-19, HIV & ARDS among others. Dr Adhikari has also collaboratively established a medical IT company called Danphe Care, where he blends his medical expertise with cutting edge technologies to create healthcare solutions to meet the needs of low- and middle-income countries. Recently he is working on developing an "electronic health record" medical software system & manufacturing medical ventilators, especially during the COVID-19 crisis. Dr. Adhikari has been providing healthcare services to the underprivileged population of Nepal through the ASK Foundation, a not-for-profit organization.

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Notes/Comments:

N/A