Active Surveillance for Safety monitoring of COVID-19 vaccines In Saudi Arabia : a Prospective 1 year study

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Background & Objective

At the end of 2019, a novel coronavirus was identified as the cause of a cluster of pneumonia cases in Wuhan, China. It is generally accepted that the world will not return to the pre-pandemic normally situation until safe and effective vaccines become available. However, the rare and unknown adverse events following immunization (AEFIs) are not usually detected in the clinical trials. Thus, monitoring the safety of COVID-19 vaccines in real-world population is very essential. Our study aims to perform a post-marketing safety surveillance of AEFIs of COVID-19 vaccines.

Methods

A prospective cohort study conducted and followed subjects who received COVID-19 vaccines from the first day of vaccination for seven days after the first and second doses, then biweekly for three months (primary objective). After that, we followed the subjects after 1 year from the first dose (secondary objective). Information from the vaccinee (demographic information, vaccine type and AEFIs) were collected by phone through a standardized online questionnaire. Baseline characteristics and AEFIs were analyzed descriptively by SPSS software. AEFIs were classified to system organ class according to medical Dictionary for Regulatory Activities (MedDRA).

Results

550 subjects of 8867 agreed to be part of the study, 240 of them were male (43.6%). The mean age of included subjects was 29.9 year. 343 (62.4%) vaccinees completed the full period of follow up. 184 (53.6%) subjects received Pfizer-BioNTech vaccine, 58(17%) subjects received AstraZeneca vaccine, 18 (5.23%) subjects received Moderna vaccine, and 83 (24.2%) subjects received two different COVID-19 vaccines

Most reported AEFIs were mild to moderate and resolved within several days , except for 21 AEFIs were serious and required medical intervention to overcome the harm. Among 343 vaccinee, 21 AEFIs reported after one year follow up of receiving COVID-19 vaccines.

Table 1: The Most common reported AEFIs according To SOC With COVD-19 Vaccines

System Organ Class	Post 1st dose			Post 2nd dose			After 1 year
	Day 0-7 days	After 2 weeks	Every 2 weeks until receiving 2nd dose	Day 0-7 days	After 2 weeks	Every 2 weeks for 3 months	After 1 year
Respiratory, thoracic and mediastinal disorders	n=11 (PF) n=4(AZ) n=1(MD)	n=5 (PF) n=1(AZ)	n=1(AZ)	n=10 (PF) n=5 (MD) n=1(AZ)	n=3(AZ) n=1 (MD)	n=6 (PF) n=2(AZ)	n= 1 (PF)
Infections and infestations disorders	n=38(PF) n=37(AZ) n=4 (MD)	n=1 (PF) n=1(AZ)		n=346(PF) n=12(AZ) n=13 (MD) n=1 (MD)	n=3(PF)		n=3(PF)
Nervous system disorder	n=33(PF) n=27(AZ) n=2(MD)	n= 1 (PF)	n= 1 (PF)	n=20(PF) n=11(AZ) n=11(MD)	n=1(AZ)	n= 4 (PF) n=1(AZ) n=1(MD)	n= 1 (PF) n=1 (AZ)
General disorders and administration site conditions	n=158 (PF) n=72(AZ) n=9(MD)	n=1(PF) n=1(MD)	n=2(PF) n=1(MD)	n=63(PF) n=23(AZ) n=19(MD)	n= 1 (PF) n=2(AZ)	n= 2 (PF) n=3 (MD) n=1(AZ)	n= 2 (PF) n=1 (AZ) n= 1 (mixed)
Musculoskeletal and connective tissue disorders	n= 13 (PF) n=12(AZ) n=1 (MD)	n=2(AZ) n= 1 (PF)	n=2 (AZ) n=1(PF)	n= 10 (PF) n=4(MD) n=7(AZ)	n=1(AZ) n=4(MD)	n=6(MD) n= 1 (PF)	n= 1 (PF) n=2 (mixed)
Gastrointestinal disorders	n=5 (PF) n=14(AZ)	n=1 (PF)	n=3 (PF)	n=2 (PF) n=2 (MD)		n=4 (PF) n=1(AZ)	n=4 (PF)

PF= Pfizer-BioNTech vaccine AZ= AstraZeneca vaccine MD= Moderna vaccine

Conclusion

The study shows the short- and long-term safety profiles of included COVID-19 vaccines are acceptable in Saudi Arabia.