



Assessment of participant-reported adverse events following the two doses of inactivated SARS-CoV-2 vaccine through a telephone survey in Türkiye

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Background

TURKOVAC™ is a whole-virion inactivated SARS-CoV-2 vaccine with conditional marketing authorization in Türkiye. The objective of this study is to assess the spectrum and the distribution of adverse events after the administration of the first 150.000 doses as a primary and booster dose in 17 provinces in Turkey.

Methods

In this cohort study, between 10 January-18 February 2022, a sample group of 20.000 people were conducted a verbal questionnaire on the 3rd and the 7th day of the first (10-17 January) and the second dose (7-18 February) vaccination through a telephone call by using a structured questionnaire algorithm. The algorithm is composed of two parts to examine both local and systemic adverse reactions. For the first dose, on the third day 6023 and on the seventh day 5345 people having received the first dose of TURKOVAC vaccine agreed to participate to the telephone survey. For the second dose, 6501 people participated to the survey on both days.

Results

Baseline characteristics of the participants is presented in Table 1. 36.6% of the participants on the 3rd day and 22.5% of the participants on the 7th day reported any adverse event following the first dose of vaccine. For the second dose on the 3rd and 7th day any adverse event rates were quite similar (35.7% and 21.9 respectively).

For both doses and on both follow-up days most reported adverse events are presented in Table 2.

For both doses, younger age, vaccine dose and female sex are associated with any adverse event and pain (on the injection site). Female sex is associated with more pain (on the injection site), swelling (on the injection site), induration (on the injection site), self-reported fever and influence on daily living.

Conclusions

In this study we conducted a rapid assessment of adverse events following two doses of TURKOVAC vaccine. The vaccine seems to have a good safety profile in the first 7 days following each dose. Younger age, vaccine dose and female sex are associated with any adverse event and pain (on the injection site). These results present valuable information for the community and may contribute to rising vaccine confidence.

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Keywords: COVID-19, vaccinology, adverse event

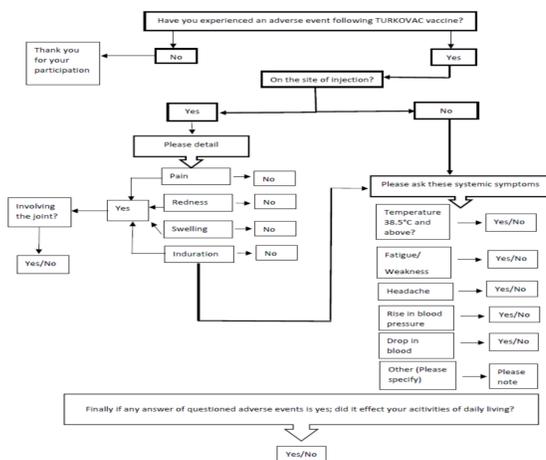


Figure 1. Questionnaire algorithm used by call center in the telephone survey following the first dose TURKOVAC vaccine, Turkey, 10-17 January 2022. The other part that stated in the algorithm is open-ended. During the survey call, other adverse events reported by the participants were noted as open-ended text.

Table 1. Baseline characteristics of the participants by follow-up day.

	1 st Dose				2 nd Dose			
	Day 3 (n=6023)		Day 7 (n=5345)		Day 3 (n=6501)		Day 7 (n=6501)	
	(n)	(%)	(n)	(%)	N	%	n	%
Sex								
Male	3585	59.5	3233	60.5	4172	64.2	4172	64.2
Female	2438	40.5	2112	39.5	2329	35.8	2329	35.8
Age Group								
19-39	1513	25.1	1310	24.5	1730	26.6	1730	26.6
40-55	2128	35.3	1909	35.7	2272	34.9	2272	34.9
56-64	1371	22.8	1243	23.3	1433	22.0	1433	22.0
65-75	878	14.6	768	14.4	936	14.4	936	14.4
76+	133	2.2	115	2.2	130	2.0	130	2.0
Mean±SD	50±14.4		50.1±14.2		49.4±14.5		49.4±14.5	
Med (Min-Max)	51 (19-91)		51 (19-89)		50 (15-90)		50 (15-90)	
Vaccine dose*								
1	728	12.1	632	11.8	-	-	-	-
2	-	-	-	-	170	2.6	170	2.6
3	3444	57.2	3064	57.3	4074	62.7	4074	62.7
4	1700	28.2	1516	28.4	2013	31.0	2013	31.0
5	151	2.5	133	2.5	244	3.8	244	3.8

*The term "vaccine dose" is used to define the number of doses of total COVID-19 vaccines including TURKOVAC vaccine as the latest dose.

Table 3. Rates of adverse events reported by the participants by follow-up day.

Adverse event	Day 3				Day 7			
	1 st Dose (n=6023)		2 nd Dose (n=6501)		1 st Dose (n=5345)		2 nd Dose (n=6501)	
	n	AE rate%						
Any adverse event	2207	36.6	2323	35.7	1201	22.5	1422	21.9
Local								
On the injection site	1789	29.7	1888	29.0	698	13.1	885	13.6
- Pain	1680	93.9	1862	98.6	662	94.8	870	98.3
- Induration	290	16.2	219	11.6	145	20.8	140	15.8
- Swelling	213	11.9	177	9.4	105	15.0	118	13.3
- Redness	49	2.7	43	2.3	42	6.0	37	4.2
Involvement of joint								
- Pain	351	20.9	266	14.3	200	30.2	194	22.3
- Induration	61	21.0	31	14.2	58	40.0	37	26.4
- Swelling	36	16.9	23	13.0	34	32.4	25	21.2
- Redness	7	14.3	4	9.3	14	33.3	5	13.5
Systemic								
Headache	479	7.9	469	7.2	426	8.0	461	7.1
Fatigue/Weakness	577	9.6	577	8.9	441	8.3	545	8.4
Other	285	4.7	135	2.1	121	2.3	210	3.2
Self-reported fever (≥38°C)	67	1.1	93	1.4	76	1.4	112	1.7
Rise in blood pressure	63	1.0	51	0.8	74	1.4	72	1.1
Drop in blood pressure	45	0.7	39	0.6	57	1.1	56	0.9
Influence on daily living	247	4.1	232	3.6	233	4.4	249	3.8