Ad26.CoV2.S vaccine safety and effectivity oddly assessed in trial

Abstract

Janssen's SARS-CoV-2 vaccine "Ad26.CoV2.S" reported 66.9% efficacy in the trial [1]. The safety and efficacy report contains certain statistics that do not hold any value without further elaboration. The protocols set to define COVID severities do not capture enough data to validify efficacy of preventive-type medicine. Self reported side effects also suggest the safety profile needs reevaluation.

Mortality and AE

Before analyzing reported adverse events we need to look at the safety and efficacy publication for this vaccine. Certain reported information is very concerning regarding making correct observations about the efficacy. In South Africa, no hospitalizations of participants with an onset of Covid-19 at least 28 days after administration occurred in the vaccine group, as compared with 6 hospitalizations in the placebo group. All five Covid-19–related deaths in the trial occurred in the placebo group in South Africa. What really stands out is that the placebo group already had a 6 times higher death rate in the pre-protocol phase. This is an extreme disparity between the death rates in the two groups. The fact that all covid related deaths occured in South Africa without additional clinical explanations that explains this disparity makes it impossible for us to assess the impact of this vaccine regarding mortality, as we did not see such phenomenons in other vaccine trials [2].

Placebo 21,888

Venous Thromboembolic Events 3

Seizures 1

Preliminary deaths 12

Total deaths 16 (COVID related = 5)

Ad26.COV2.S 21,295

Venous Thromboembolic Events 11

Seizures 4

Preliminary deaths 2

Total deaths 3

VTE

Non-placebo group	*11 cases*	*related* to the vaccine*
Placebo group	*3 cases*	*related* to the placebo*

**Relationship to vaccine or placebo was determined by the Principal Investigator.*

We are not aware of any likely way VTE could happen with a 6 day onset of symptoms due to the placebo vaccination which is a 0.9% sodium chloride solution [3][4]. Due noted, 11 placebo participants were given the wrong dose or injection.

The patient that was determined as placebo related VTE did not recover from the suffered deep vein thrombosis. The following additional information was provided about this person:

Age = 44	*Gender = Male*	*Onset days = 6*	*Recovered = No*	*Related = No*

"3 paternal uncles with deep vein thrombosis, 4.5- hour air travel 4 days after vaccination (1 day to onset of symptoms)"

We can not know whether genetics or traveling [5] played a role with any certainty, but there is no additional information provided on how the placebo injection caused this adverse event.

We noted another case in the non-placebo VTE list that was quite confusing with the provided data and elaboration. This individual suffered from a transverse sinus thrombosis and cerebral hemorrhage.

Age = 25	*Gender = Male*	*Onset days = 21*	*Recovered = Yes*	*Related = No*

"Event most likely resulted from multiple predisposing factors including pre-existing cerebral sigmoid sinus stenosis that predisposed the participant to cerebral venous thrombosis, and an infection with an unknown organism that started 8 days following vaccination, triggering inflammation and a hypercoagulable state. Thrombocytopenia was also observed. Subsequent testing identified anti-PF4 antibodies at the time of the event."

Several studies have shown that high levels of anti-PF4 antibodies are present in samples from patients with vaccine-induced immune thrombotic thrombocytopenia [6]. Classifying this adverse effect as unrelated to vaccination seems unreasonable at all times to us during safety research [7].

Protocol

According to the trial protocol if a person is tested positive for COVID-19, and develops a cough and headache together it is already considered “moderate” COVID. Historically observing these symptoms would only suggest a mild cold [8]. The group of participants chosen for this trial had a median BMI of 27, which is classified as Grade I obesity [9]. 40.8% of the participants had 1 or more (severe) comorbidities.

Saying the Janssen vaccine is safe and effective for any demographic is impossible based on the provided data. There was a 6x amount of deaths in the pre-protocol phase in the placebo group, yet a 3.6x amount of VTE in the non-placebo group. Which is a contrasting difference (fig 1). Suggesting one group having a better general health than the other is not a realistic explanation for the increased VTE.

Another thing we did not see in the Janssen research is studying subclinical organ health after viral exposure. It’s known that brains [10][11][12], hearts [13], livers [14], lungs[15] and kidneys[16] can be damaged due to this virus. Ignoring such things while classifying 2 mild symptoms as moderate covid is disingenuous [17], as it could mean mitigating a mild symptom is considered efficacious against moderate covid, while disregarding direct and indirect long term damage (including reasons behind “long-covid”) [18].

Shortness of breath, pericarditis, dizziness, elevated heart rate, palpitations, chest pains, chest discomfort, syncope, presyncope, fatigue can be red flags that can suggest a cardiovascular problem like myocarditis or pericarditis. Underdiagnosis could occur due to some of these symptoms being listed as allergic reaction indicators in the Janssen EMA approved documentation [19]. It is reported that the Jansen vaccine can cause myocarditis even with only 1 injection [20][11]. Myocarditis is often subclinical in young men [22][23]. Pericarditis or myocarditis is not listed as a possible side effect. There was a single case of pericarditis in the trial’s non-placebo group.

Discussion

Safety and efficacy information given on the Ad26.CoV2.S vaccine is inconclusive. The protocols are not conclusive enough to make an assessment on safety [24][25][26] and efficacy. The claimed durability is not captured in the provided data either [27]. In The Netherlands where this vaccine is widely used, the most adverse events reported are in a low risk age group (20-29 years old) according to the self-report service for the Dutch Medicines Evaluation Board [28]. Myocarditis and pericarditis reports per injection are higher compared to the Pfizer-BioNTech vaccine. Which suggests reevaluating pericarditis and myocarditis as a side effect with a more balanced protocol and selection.

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