Safety and Reactogenicity of Covid-19 (Recombinant) Vaccine Doses Administered in 4-, 8- or 12-Weeks Intervals Between the First Two Doses.

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INTRODUCTION

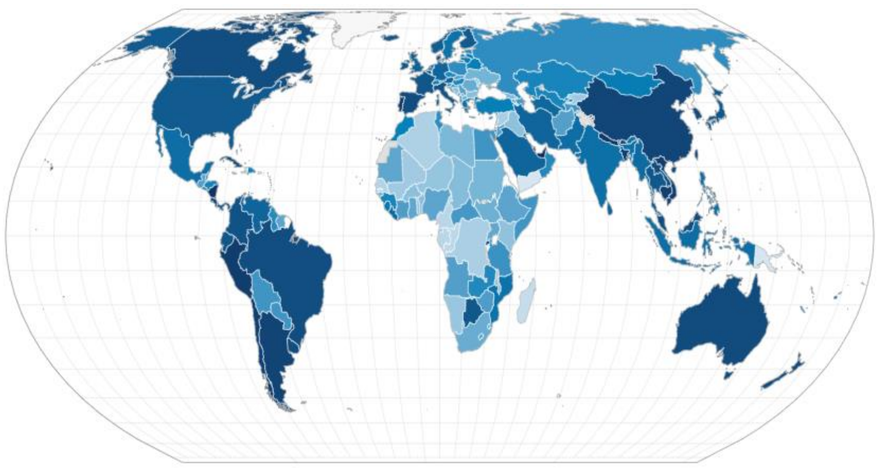
COVID-19 is featured as a wide clinical spectrum disease, varying among asymptomatic to severe cases and death.

- Pandemic status was declared on 03/11/20.

One of the best medical approaches for halting the spread of infectious diseases is vaccination (ASEFA *et al.*, 2023).

COVID-19 vaccines significantly reduced COVID-19 morbi/mortality and contributed to the pandemic end (WHO, 2024).

Percentage of total population vaccinated with at least one dose of a COVID-19 vaccines



% of total population Min 4% Max 100%

OBJECTIVE

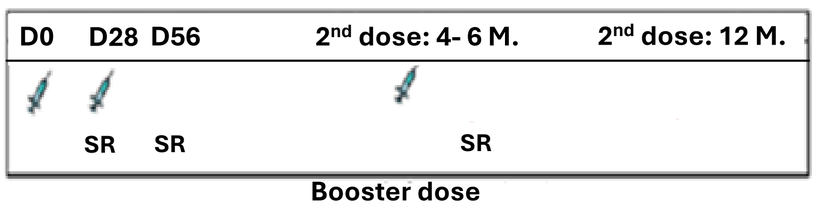
To follow up the safety and reactogenicity of three covid-19 (Recombinant) vaccine doses administered in 4-, 8- or 12-weeks intervals between the first two doses.

METHODOLOGY

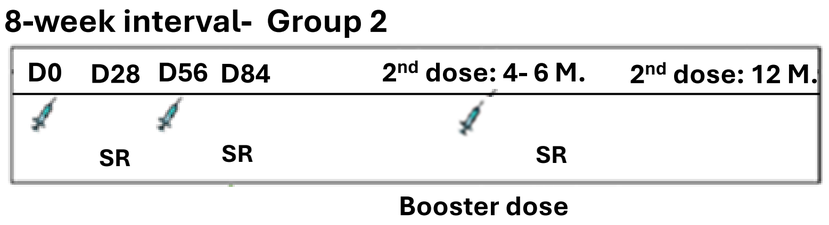
- Phase IV open, randomized, multicenter clinical trial. Intention-to-treat analysis: all vaccinated participants with security data in one post-vaccination follow up at least.

- The solicited Adverse Events (AE) were registered by the participants within seven days of vaccine administration for three doses.

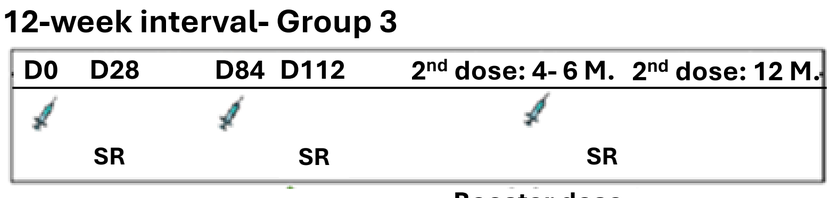
4-week interval- Group 1



8-week interval- Group 2



12-week interval- Group 3



***SR were obtained 28 days after covid-19 (recombinant) Fiocruz/AstraZeneca doses**

Subtitle:

M: Months later

Vaccine dose

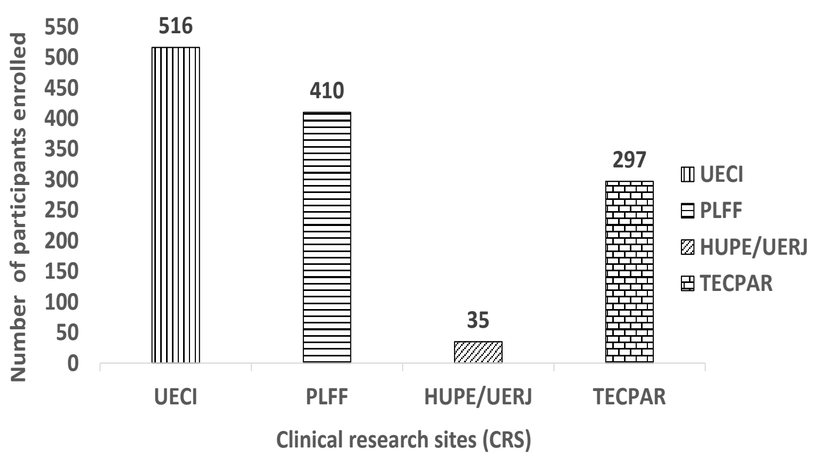
SR: Collection of Safety & Reactogenicity information

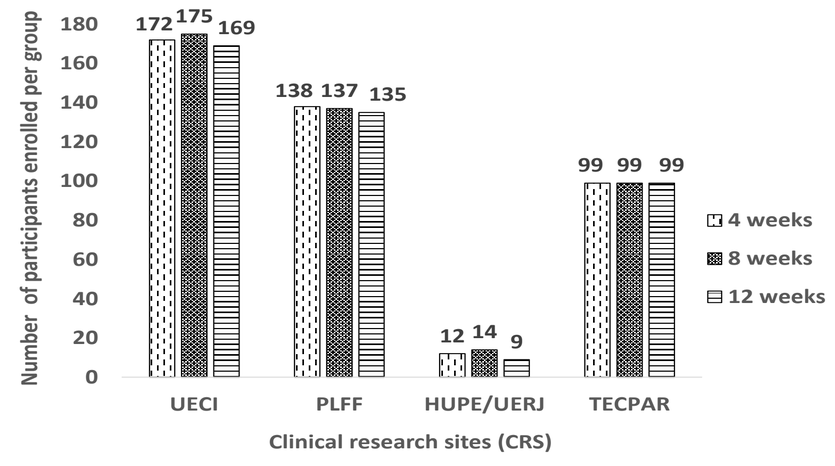
RESULTS

Enrolled participants

1,258 participants were randomized and received the first dose of covid-19 (Recombinant) vaccine.

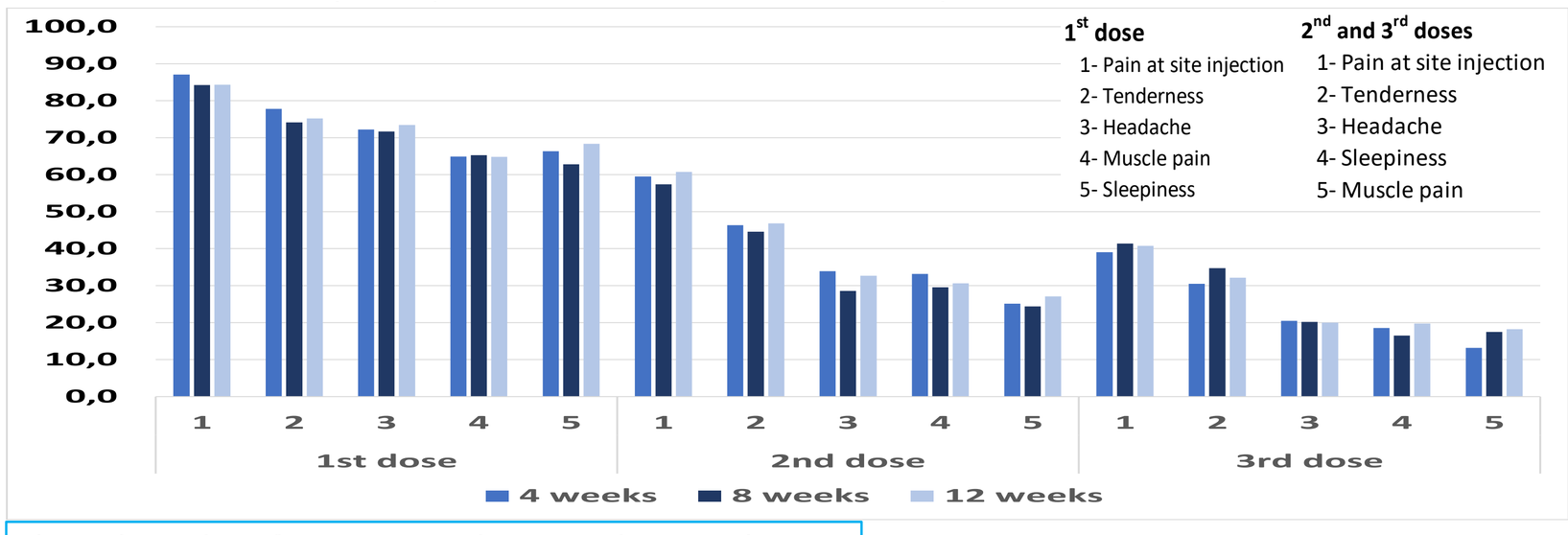
Enrolled participants per group in the CRS





Solicited AE frequency after 3 doses of covid-19 (Recombinant) vaccine.

Data from 1,211 participants were considered as IT analysis.



The solicited AE frequency reduces as dose evolution.

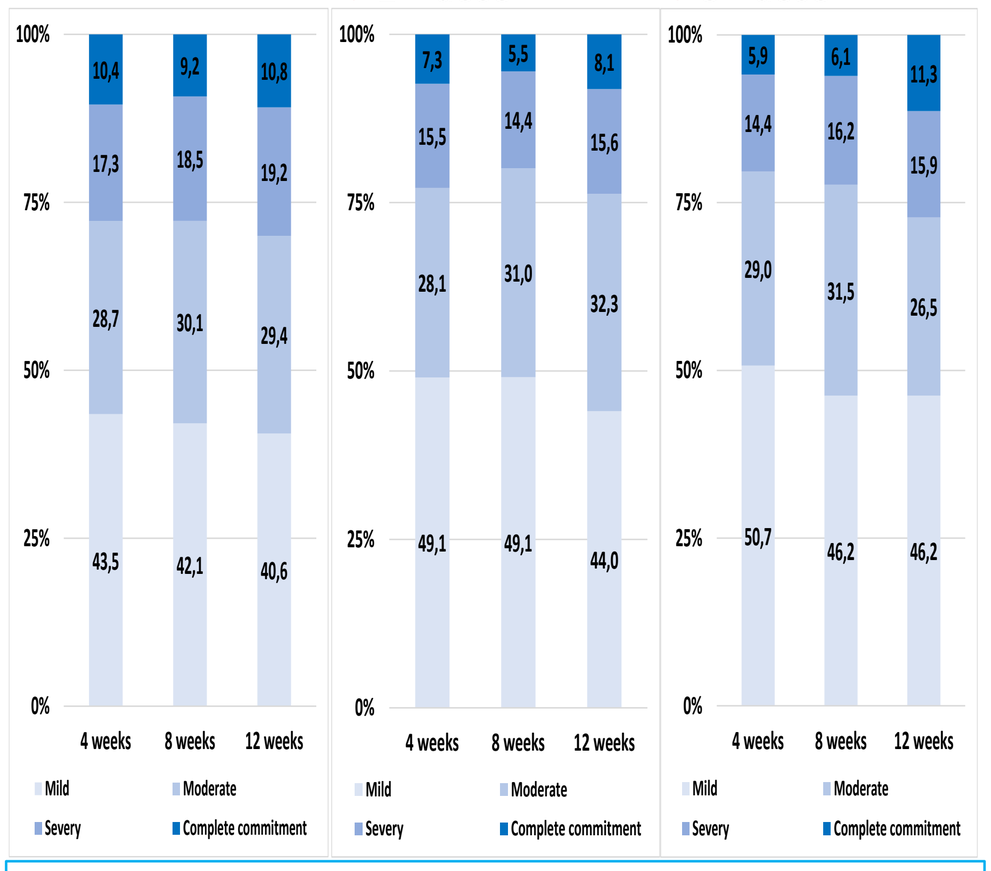
Solicited AE time duration (days)

Solicited Adverse Events	Group		
	4 weeks	8 weeks	12 weeks
1 st dose			
Pain at site injection	3,1	3,1	3,1
Tenderness	2,8	2,6	2,7
Headache	1,9	1,7	1,8
Muscle pain	1,7	1,7	1,7
Sleepiness	1,7	1,6	1,7
Malaise	1,3	1,3	1,3
Fatigue	1,4	1,3	1,4
Chills	0,9	1,0	1,0
Joint pain	1,0	0,9	1,1
Fever	0,5	0,5	0,6
2 nd dose			
Pain at site injection	1,5	1,6	1,7
Tenderness	1,2	1,2	1,3
Headache	0,8	0,7	0,9
Sleepiness	0,9	0,7	0,8
Muscle pain	0,7	0,6	0,7
Fatigue	0,6	0,5	0,6
Malaise	0,5	0,4	0,5
Oedema at site injection	0,3	0,5	0,5
Flu-like symptoms	0,4	0,3	0,4
Joint pain	0,3	0,3	0,4
3 rd dose			
Pain at site injection	1,3	1,5	1,5
Tenderness	1,0	1,2	1,2
Headache	0,7	0,7	0,6
Sleepiness	0,6	0,6	0,7
Muscle pain	0,4	0,6	0,7
Fatigue	0,5	0,4	0,6
Oedema at site injection	0,4	0,5	0,5
Malaise	0,4	0,4	0,4
Joint pain	0,3	0,3	0,4
Redness	0,2	0,3	0,2

8 solicited AE were common and resolved in a few days for all 3 doses.

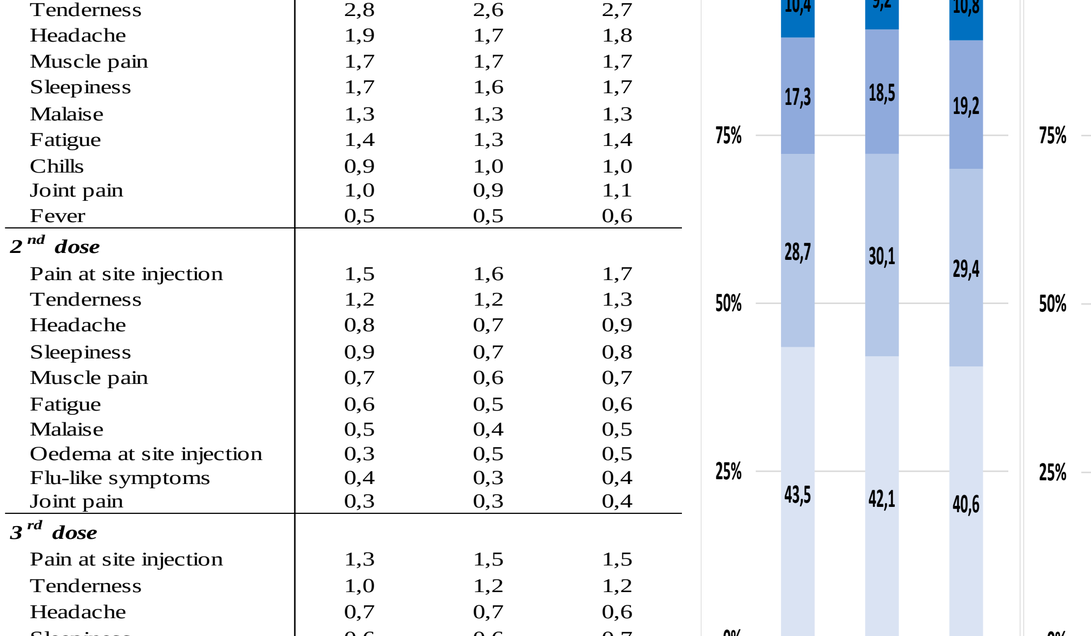
Solicited EA severity after each dose per group

1st dose | 2nd dose | 3rd dose



Regardless of the 4-, 8- or 12- weeks intervals, the solicited EA were mostly mild or moderate for 3 doses.

AE resolution and health care services



Less than 2.5% of doses induced AE, which needed medical care service.

The hospitalizations were not classified as related to vaccine.

There were no ICU-hospitalizations nether VITT cases.

ClinicalTrials.gov: NCT05157178

CONCLUSION

The safety and reactogenicity follow up of 3 doses shows that most AE were not severe and resolved in few days after covid-19 (Recombinant) vaccine, whether administered in 4-, 8- or 12-weeks intervals between the first two doses.