Safety and long-term immunogenicity of BNT162b2 vaccine in individuals with Down syndrome

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Aims

1. To evaluate the safety of BNT162b2 vaccine in individuals with DS
2. To measure SARS-CoV-2 specific antibodies
3. To correlate the humoral immune response of individuals with DS with those of the HCs

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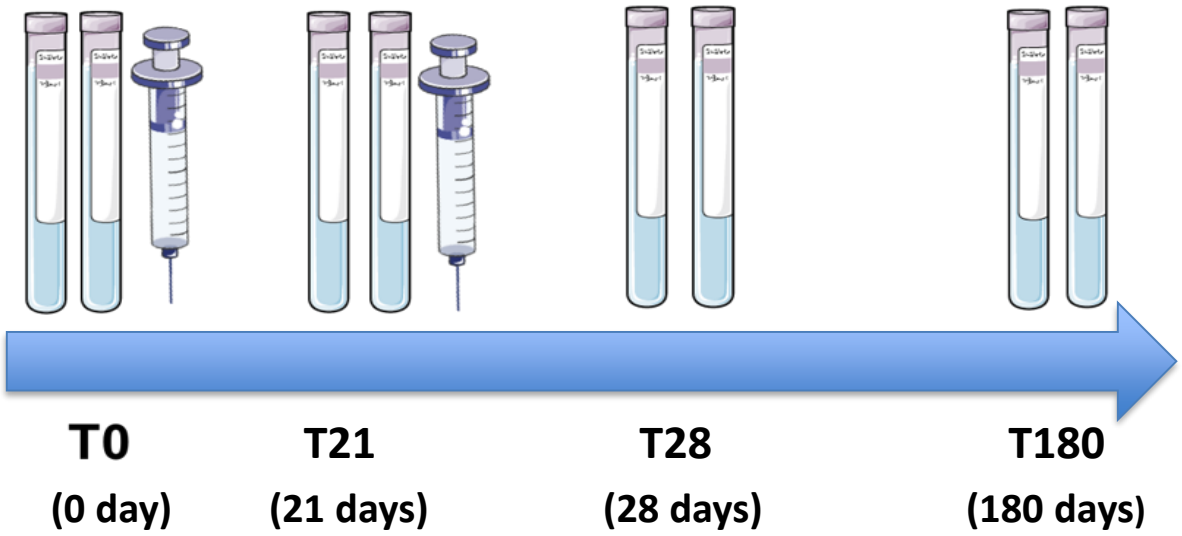
Study Design



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Study Design

The adverse events questionnaire

Local and systemic adverse events were defined:

- **MILD** if reaction went away on its own
- **MODERATE** if a clinic visit, or hospital admission were needed
- **SEVERE** if the reaction was immediately life threatening, or if reaction led to disability, or death of the patient

Inclusion criteria

- Down syndrome with age ≥12 ys
- No history of SARS-CoV2 infections

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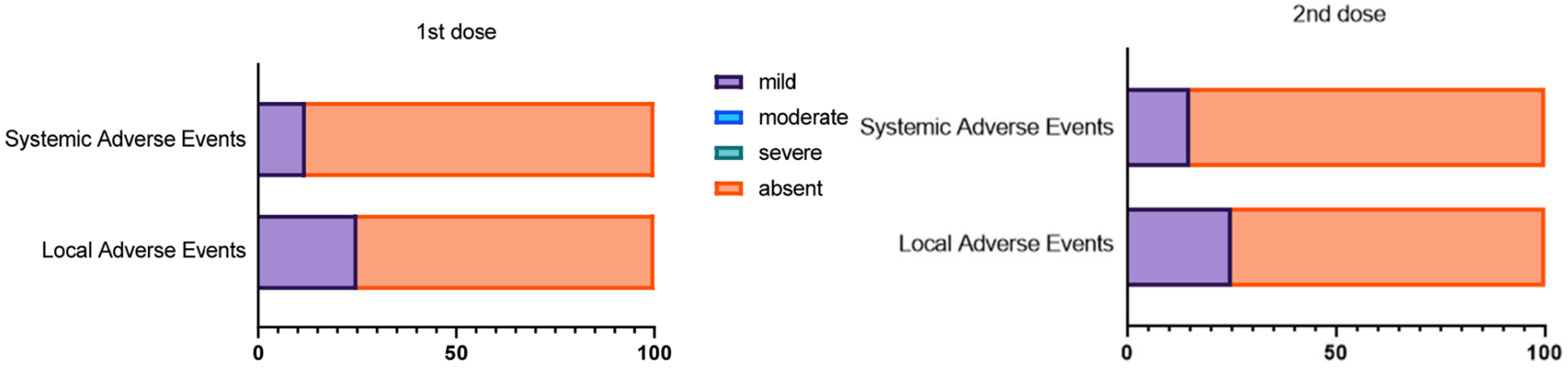
Patients' characteristics	DS *n*=40	HC *n*=36	*p* Values
Females, *n* (%)	17 (42.5%)	23 (63.9%)	n.s.
Age, mean (+/- SD)	17.90 (± 4.59)	47.4 (±12,2)	<0.0001
Ethnicity, *n* (%)	Black 2.5% East Asian 5% Latin American 10% **White 82.5%**	n.a.	n.a.
Type of trisomy, *n* (%)	**Full/standard 92.5%** Mosaic 0% Translocation 0% Don't known 7.5%	n.a.	n.a.
Level of intellectual disability, *n* (%)	Mild 30% **Moderate 37.5%** Severe/profound 12.5% Don't known 20%	n.a.	n.a.

Patients' characteristics	DS *n*=40	HC *n*=36	*p* Values
Comorbidities, *n* (%)	**Congenital heart disease 60%** Recurrent respiratory infections 12.5% **Thyroid disease 52.5%** Caeliac disease 7.5% **Obstructive sleep apnea 37.5%** Obesity 22.5% Hypertension 2.5% Chronic liver disease 7.5% Chronic lung disease 5% GERD 15% Allergies 5% Psychiatric disease 12.5%	n.a.	n.a.

Adverse events



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	n = 40 1° Dose	n = 40 2° Dose
Systemic adverse events	5 (12,5%)	6 (15%)
Fever	2/5	4/6
Wheezing	1/5	0
Muscle pain	1/5	1/6
Fatigue	1/5	2/6
Headache	1/5	1/6
Chills	1/5	0
Dizziness	1/5	0
Cough	1/5	1/6
Local adverse events	10 (25%)	10 (25%)
Pain at the site of injection	10/10	10/10
Redness at the site of injection	1/10	2/10

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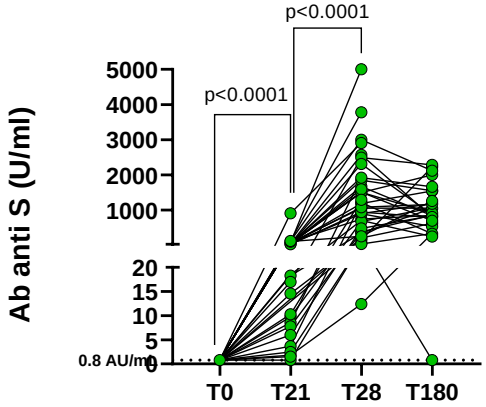
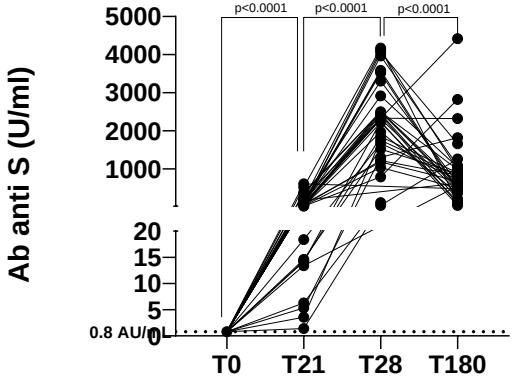
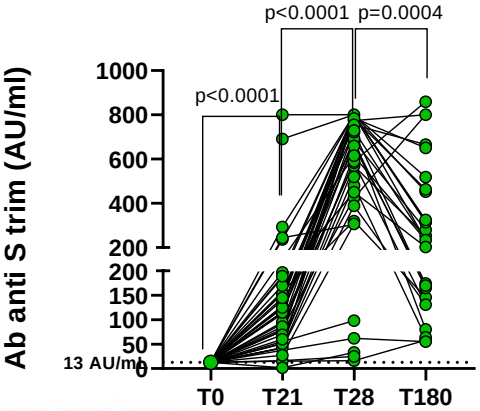
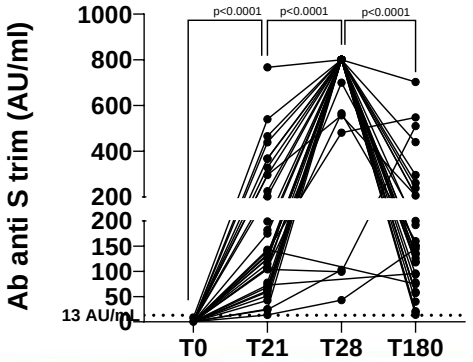
Humoral responses









DS
HC

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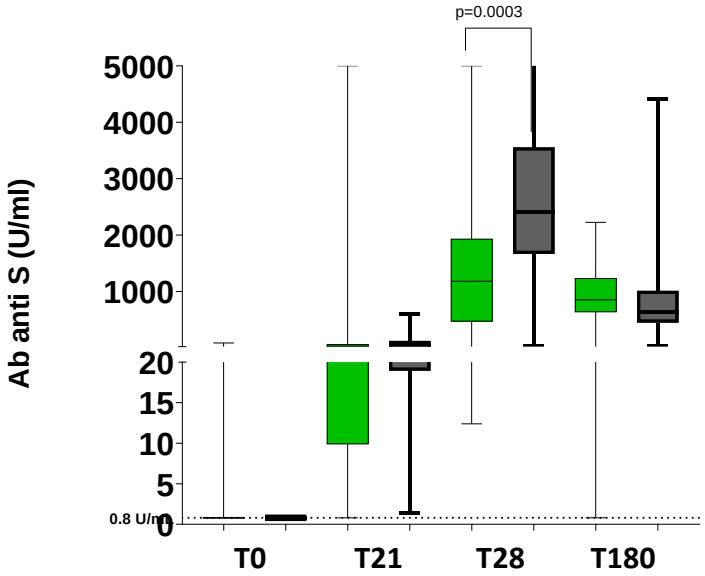
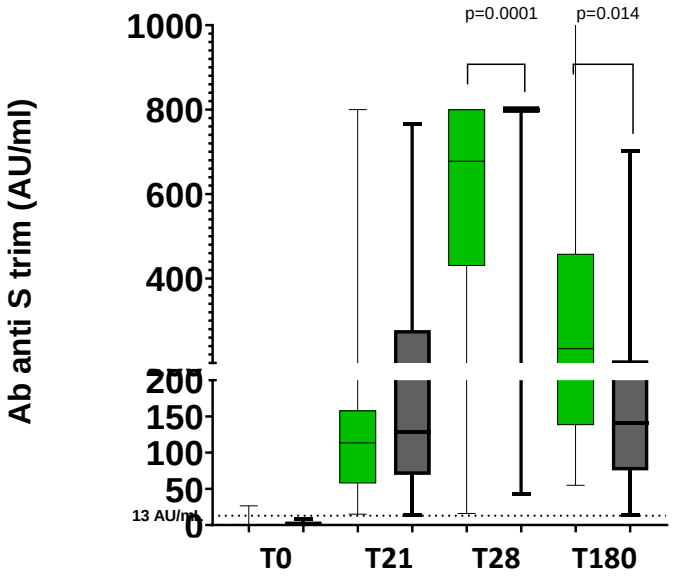
Comparison of the antibody responses





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Conclusions

- Good safety profile of BNT162b2 vaccine for individuals with DS
- Side effects of the BNT162b2 vaccine are similar to the general population
- BNT162b2 vaccine is highly effective in this population, as measured by Ab levels, only one patient with DS showed no sieroconversion after the first dose

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Conclusions

- People with DS should be prioritized for COVID-19 vaccine: the Ab levels of individuals with DS are lower than those of HCs after the second dose
- It is necessary to do booster doses of vaccine: the Ab levels wane overtime in both groups (DS + HCs)

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Limits

- Small sample size
- The lack of age-matched controls

What's next?

- Analyzing SARS-CoV2 specific T and B cells after BNT162b2 vaccine
- Sharing our data on the humoral response with other research groups
- Comparing the humoral responses to BNT162b2 vaccine of individuals with DS with other vulnerable populations

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Individuals with DS and their parents

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