Antibody response to SARS-CoV-2 vaccines and immunodeficiency: a randomized trial

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BACKGROUD

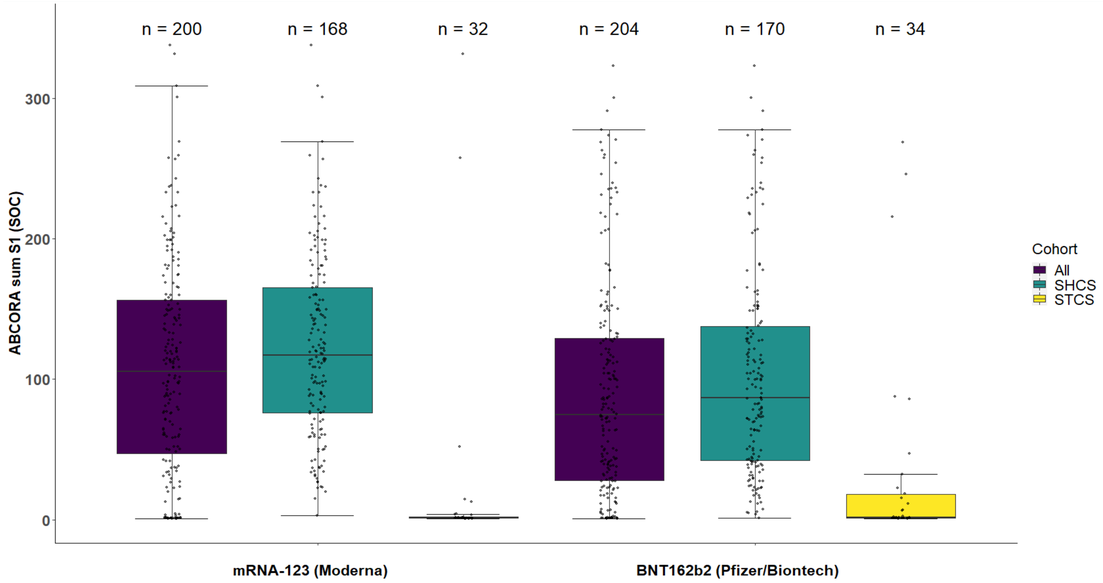
- Assess non-inferiority of BNT162b2 to mRNA-1273 in immunocompromised patients in terms of immune response 8 weeks after second vaccination.

Since January 2021, the two in Switzerland approved severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA vaccines BNT162b2 (Pfizer/Biontech) and mRNA-1237 (Moderna) have been used to vaccinate the Swiss population. These vaccines were found to be safe in licensing trials with excellent efficacy of 95% and 94% in terms of preventing COVID-19 illness 14 days after the second vaccination. However, randomized evidence on the comparative effectiveness of both vaccines in immunocompromised patients is lacking

METHODS

- Parallel, two arm (allocation 1:1) open-label, non-inferiority randomized clinical trial (RCT) nested into the Swiss HIV Cohort Study (SHCS) and the Swiss Transplant Cohort Study (STCS)
- Antibody response to SARS-CoV-2 spike (S1) protein receptor binding domain using Elecsys® Anti-SARS-CoV-2 S assay from Roche (binary, cut-off ≥0.8 Units/ml) 12 weeks after first vaccination (8 weeks after second vaccination)
- Non-inferiority if the lower limit of the 95% confidence interval difference in antibody response proportion > -10%
- Secondary outcome: sum of S1 signal over cut-off values of IgG, IgA, IgM using the Antibody CORonavirus Assay (ABCORA)

Antibody response 8 weeks after second vaccination with mRNA-1237 (Moderna) is non-inferior to BNT162b2 (Pfizer) in immunocompromised patients.



RESULTS

- 430 patients randomized
- Antibody response for mRNA-1237
  92.1% (95% CI 88.4;95.8%; 186/202)
- Antibody response for BNT162b2
  94.3% (95% CI 91.2;97.4%; 198/210
- Difference: -2.2% (95% CI -7.1;2.7%)

- Mean ABCORA sum S1 levels for mRNA-1273:
  107.2 (95% CI 96.7-117.9) overall
  123.5 (95% CI, 113.5-133.4) in HIV patients
  22.1 (95% CI, 0.0-48.4) in solid organ transplant
- Mean ABOCRA sum S1 levels for BNT162b2:
  90.6 (95% CI 80.0-101.3) overall
  102.3 (95% CI, 91.2-113.4) in HIV patients
  32.1 (95% CI, 7.5-56.7) in solid organ transplant

CONCLUSIONS

- mRNA-1237 is non-inferior to BNT162b2
- HIV patients had a good antibody response
- High proportion of transplant recipients had no antibody response

Nearly 80% of patients with solid organ transplant have not developed neutralizing activity and need booster vaccination.

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