

Psychological impact and side effects/adverse events after the first dose of BNT162b2 Sars-CoV-2 vaccine

The following *ad hoc* clinical-generated anonymous questionnaire is administered to patients who received SARS-CoV-2 vaccine (BNT162b2) at the Department of Oncology of San Luigi Gonzaga University Hospital, from 31st March 2021 to 19th April 2021.

The questionnaire is composed by two parts: the first is dedicated to patient's oncological history and may be compiled with the assistance of a medical doctor during the clinical examination before vaccination. The second part is focused on the psychological and social impact of vaccination and side effects/adverse events occurred after the first dose of BNT162b2, SARS-CoV-2 vaccine.

By compiling the questionnaire the patient accepts to be questioned about the side effects/adverse events experienced after the second dose via telephone questionnaire that will be administered 4-7 days after.

By compiling the anonymous questionnaire, the patient attests to have read and understood the information above and gives the informed consent for this observational study.

All data collected will be kept confidential in compliance with the current regulations.

1st PART: Oncological history

| Type of malignancy | | Therapy | |
|----------------------------|--|-------------------------------------|--|
| Thoracic (lung or pleural) | | Chemotherapy (ChT) | |
| Gastrointestinal | | Immune-checkpoint inhibitors (ICIs) | |
| Prostate | | ChT-ICIs | |
| Breast | | Other systemic therapies | |
| Genitourinary | | Targeted therapy | |
| Endocrine | | Hormone therapy | |
| Gynaecological | | Locoregional treatment | |
| Others | | Newly diagnosed patient | |
| | | Follow-up | |
| | | Stage disease | |
| | | Early-stage | |
| | | Advanced disease | |
| | | Disease-free | |

2nd PART: Patient's section

| General information | | |
|---|-----|----|
| Age | | |
| Sex | M | F |
| SARS-CoV-2 infection history | | |
| Have you ever been infected by SARS-CoV-2? | Yes | No |
| If yes, please specify the period when the infection occurred: <ul style="list-style-type: none"> • From March 2020 to May 2020; • From June 2020 to September 2020; • From October 2020 to January 2021. | | |
| If yes, specify the health-care assistance you have received: <ul style="list-style-type: none"> • None, an asymptomatic infection occurred; • Home care assistance; • Hospitalization (low intensity of care); • Hospitalization (intensive care unit). | | |
| Vaccine | | |
| Before receiving the first dose of BNT162b2 SARS-CoV-2 vaccine, you felt a sense of: | | |
| Fear | Yes | No |
| Insecurity | Yes | No |
| Indifference | Yes | No |
| Confidence | Yes | No |
| Enthusiasm | Yes | No |
| After receiving the first dose of BNT162b2 SARS-CoV-2 vaccine, you felt a sense of: | | |
| Fear | Yes | No |
| Insecurity | Yes | No |
| Indifference | Yes | No |
| Confidence | Yes | No |
| Enthusiasm | Yes | No |
| After receiving BNT162b2 SARS-CoV-2 vaccine you feel: | | |
| More confident in visiting public places (i.e. cinemas, malls) | Yes | No |
| More confident in spending time with your family/friends | Yes | No |
| More confident in attending check-up visits | Yes | No |
| More confident in practising recreational and sport activities | Yes | No |
| You consider information you have received about SARS-CoV-2 vaccine prior to recruitment in the vaccine campaign: | | |
| Insufficient | Yes | No |
| Confused | Yes | No |
| Adequate | Yes | No |

| | | |
|---|-----|----|
| Your own opinion about SARS-CoV-2 vaccine has been mostly influenced by: | | |
| <ul style="list-style-type: none"> • General practitioner/oncologist or other specialists; • Family/friends; • Mass-media; • Scientific literature. | | |
| Would you have accepted to be vaccinated if you were proposed a different serum? | Yes | No |
| Patient's allergy history | | |
| Do you suffer from any form of allergy (any food or drugs)? | Yes | No |
| Have you ever received an allergological examination? | Yes | No |
| If yes, have you been prescribed an anti-allergic prophylaxis before receiving the vaccine? | Yes | No |
| Have you been recommended to be clinically observed more than fifteen minutes after receiving the vaccine? | Yes | No |
| Side effects/adverse events | | |
| Have you experienced any side effect/adverse event after the first dose of BNT162b2 SARS-CoV-2 vaccine? | Yes | No |
| If yes, please specify the type of side effect/adverse event | | |
| Injection site pain/rash | Yes | No |
| Diffuse joints pain | Yes | No |
| Fever | Yes | No |
| Chills or night sweating | Yes | No |
| Headache | Yes | No |
| Nausea, vomit or diarrhea | Yes | No |
| Fatigue | Yes | No |
| Insomnia | Yes | No |
| Lymph nodes enlargement | Yes | No |
| Mild allergic reaction (rash, diffuse pruritus) | Yes | No |
| Severe allergic reaction (dyspnoea, anaphylaxis) | Yes | No |