

Appendix

Part A: Trial flow

Part B: Instructions for study participant - immunosuppression management

Part C: Questionnaire for adverse events

A. Trial flow

Invitation for a first study visit:

Kidney transplant recipients > 6 months post transplant; and ≥ 3 weeks post 2nd vaccine

First visit: informed consent; anti-spike antibody test; tacrolimus levels; written instruction for the following steps provided (See Appendix part B)

Between first and second visit:

Negative serology -> randomization of participants in the randomized controlled trial (RCT) to no intervention or immunosuppression reduction -> study coordinator instructions for RCT participants by phone*

Second visit: vaccination for all participants (observational and RCT); further instructions for RCT participants on the intervention

Follow up since vaccination:

At 2 weeks: serology all, T-cell assay for subset, adverse events, other evaluations **

At 3 months: serology all, T-cell assay for subset, other evaluations **

At 6 months: serology all, T-cell assay for subset, other evaluations **

At 12 months: serology all, T-cell assay for subset, other evaluations **

* No intervention arm – do not change immunosuppressive regimen;

immunosuppression reduction arm – stop mycophenolic 4 days before second visit

(vaccination) and resume one week after vaccination

** Evaluation for kidney rejection (creatinine at each visit) and SARS-CoV-2

infection (patient interview and data from computerized records)

B. Instructions for study participant - immunosuppression management

Dear participant,

You participate in this randomised controlled trial to evaluate the safety and effectiveness of a booster (third) dose of mRNA SARS-CoV-2 BNT162b2 vaccine with or without immunosuppression reduction.

In this study you will be randomised by a computer to be in one of two arms of the study. Following randomization, you will be informed by the study coordinator, who is a nurse in the transplantation clinic, to which arm you belong:

Arm 1 – immunosuppression continuation: continue with your medications as usual before and after the third vaccine injection date.

Arm 2 - immunosuppression reduction: stop taking Myfortic or Cellcept from 4 days before your scheduled vaccine date and 7 days after. Please continue with all your other medications as usual. 4 days before the vaccine – if the vaccine is on Thursday, you stop Myfortic or Cellcept on Sunday and resume on next Thursday; if the vaccine is on Wednesday, you stop Myfortic or Cellcept on Saturday and resume on next Wednesday.

If you have any questions, don't hesitate to contact the study team and/or the transplantation clinic.

C. Questionnaire for adverse events

Did you have any of these symptoms after the first vaccine injection?

1 st vaccine date:	yes	No	Severity
Local pain on injection site			
Muscle pain			
headache			
Fatigue			
Allergic reaction			
Fever			
Lymph node enlargement			
Need of medical treatment			
Need of hospitalization			

Did you have any of these symptoms after the second vaccine injection?

2 nd vaccine date:	yes	No	Severity
Local pain on injection site			
Muscle pain			
headache			
Fatigue			
Allergic reaction			
Fever			
Lymph node enlargement			
Need of medical treatment			
Need of hospitalization			

