Vitamin D Supplementation Trial 2 Month / 3rd Visit CRF



TO BE COMPLETED BY RESEARCHER

1. Is the participant's urine ca:cr ratio from	Yes No				
visit 1 within the acceptable range?*	Voc No No				
2. Is the participant's serum calcium from	Yes No No				
visit 1 within the acceptable range?*					
Researcher's signature and ID	Date				
iSTAT results					
3. POC ionised calcium (mmol/l)**	1^{st} 2^{nd} – if required 3^{rd} – if required				
Researcher's signature and ID	Date				
4. Other study bloods	Collected? Yes No				
Site of procedure (e.g. left arm)					
5. Urine sample (for ca:cr ratio)	Collected? Yes No				
Researcher's signature and ID	Date				
6. Is the participant's ionised calcium from	Yes No No				
this visit within the acceptable range?*					
Researcher's signature and ID	Date				
7. Have there been any changes in the participant's health in the last 4 weeks? Yes No					
7. Have there been any changes in the participant's health in the last 4 weeks? Tes NO					

7a. If yes, please complete the table below and an AE or SAE form if applicable.

Change in health	Date	Time	Description	Adverse Event / Serious Adverse Event form completed? (Y/N)
Researcher's signature and I	D		Date	
8. Date and time of administ	ration o	f studv me	dication (please ensure acc	ceptable safety readings
before administering).			and the fire and a constant and	septuale salety readings
Researcher's signature and I	D		Date	
9. Any comments / actions to	aken?			
Researcher's signature and I	D		Date	
Nescarcifer's signature and in				

Additional notes

- * Ensure the safety measurements collected at the previous visit are within the acceptable ranges before proceeding with this visit (serum calcium <2.65mmol/l; urine ca:cr <1). If the measurements are found not to be acceptable the participant cannot proceed in the trial.
- **Ensure the iSTAT measurement is within the acceptable range before proceeding with this visit (ionised calcium <1.3mmol/l). If the measurement is found not to be acceptable repeat the measurement. If the second measurement is within the acceptable range, take a third measure. If two of three measurements are normal proceed with this visit. If two of three measurements fall outside of the acceptable ranges do not proceed with this visit. If the second test is unacceptable, as well as the first, do not carry out a third test. The participant cannot proceed in the trial.

If the participant cannot continue in the trial, collect a blood sample to enable laboratory analysis of serum calcium for reporting to the participant's GP as appropriate. There is no need to collect the other trial bloods.