NIHR | National Institute for Health Research

UNIVERSITY OF BIRMINGHAM | BCTU

VITDALIZE

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VITDALIZE UK Site Initiation Training

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Effect of High-Dose Vitamin D3 on 28-Day Mortality in Adult Critically Ill Patients with Severe Vitamin D Deficiency

The UK arm of an International Multi-Centre, Placebo-Controlled, Phase III Double-Blind Trial

Protocol Version 7.0, 29th May 2025

Presentation version 11.0 – 28th July 2025

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Sponsor:
University of Graz, Austria

National Co-ordinating Centre:
University of Birmingham

Funder:
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Agenda

Background & Objectives → Trial Design & Procedures → Data Management → Pharmaco-vigilance → Quality Control & Assurance

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VITDALIZE UK

- VITDALIZE is an international trial and is a collaboration between Austria, Belgium, Germany and the UK
- The target number for the international trial is 2400
- Estimated recruitment end: Mid-2026
- Length of follow-up: main trial data collection ends at **death or at one year follow-up**, whichever occurs first

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Background

- Vitamin D deficiency (VDD) is common in patients admitted to intensive care units (ICU) with prevalence between 40-70%
- It has been identified that patients who have VDD are associated with poor outcomes in critical illness
- VDD has been associated with:

• Acute respiratory failure • Duration of mechanical ventilation • Sepsis	• Nosocomial infection • Acute kidney infection • Increased mortality

- Patients who are VDD have a longer ICU stay, increased morbidity and mortality

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- In most cases, patients enter ICU in a deficient state due to pre-existing conditions
- However, vitamin D levels can also fall rapidly after ICU admission
- In the past decade vitamin D has been associated in the function of a wide range of tissues including the immune system
- Vitamin D has the ability to act synergistically on the immune response
- Previous research into vitamin D has been criticised due to:
  - Small number of patients recruited
  - Single centre trials
  - Vitamin D given as a single dose
  - Critically ill patients with severe VDD not included

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VITdAL-ICU pilot trial

- Recruited 475 patients
- Only phase III trial of high dose vitamin D3 supplementation (540,000IU followed by monthly 90,000IU for 5 months) in critical illness

Findings

- No difference was found in the primary endpoint of length of hospital stay between placebo and high-dose vitamin D3 treated patients
- However, a non-significant, absolute risk reduction in all-cause hospital mortality was found. The difference was large (17.5%) and significant in the predefined subgroup of patients with severe VDD (25(OH)D ≤12ng/mL)
- This was a secondary endpoint in the predefined subgroup with severe VDD and was hypothesis generating leading to the VITDALIZE Trial

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Trial rationale

- There are associations between VDD and poor outcomes in sepsis, acute kidney injury and acute respiratory failure in critical illness
- Limited number of interventional trials of vitamin D replacement in ICU
- Vitamin D testing is available in all NHS hospitals and is inexpensive

Aim

To determine if treatment with high dose vitamin D improves patient outcomes and is cost-effective when compared to placebo in severely VDD patients critically ill patients admitted to ICU

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Primary objective

- To determine whether treating severe VDD with high dose vitamin D3 replacement in adult critically ill patients decreases 28-day mortality

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Secondary objectives

To determine whether treating severe VDD with high dose vitamin D3 replacement in adult critically ill patients:

- Reduces organ dysfunction
- Reduces hospital and ICU length of stay
- Reduces mortality
- Improves long-term survival
- Reduces readmission to hospital
- Improves activities of daily living

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Secondary objectives

In the UK additionally:

- Improves health-related quality of life at 90 days and 1 year
- Reduces disability at 90 days and 1 year
- Reduces health care utilisation to 1 year
- Is cost-effective in the NHS setting

Exploratory objective

- To assess the feasibility of patient quality of life and disability at day 0

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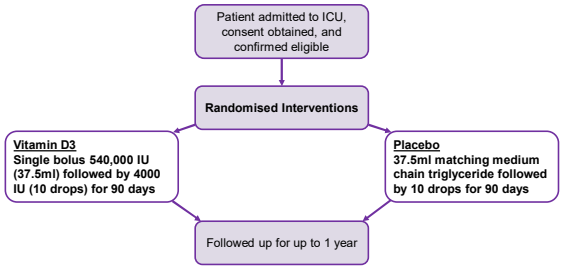
Summary



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Eligibility

Inclusion Criteria

1. Patients ≥ 18 years
2. Anticipated ICU stay ≥ 48 hours
3. Admission to ICU ≤ 72 hours before screening for VDD
4. Severe VDD (25(OH)D ≤ 12ng/ml (30nmol/L)) after ICU admission

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Eligibility continued

Exclusion Criteria

1. Severe gastrointestinal dysfunction (>400ml nasogastric tube residual volume)/unable to receive trial medication
2. Not expected to survive initial 48 hours of admission or treatment withdrawal imminent (within 24 hours)
3. Patient with DNAR orders in place
4. Hypercalcemia (>2.65 mmol/l corrected calcium and/or >1.35 mmol/l ionized calcium at screening)
5. Known kidney stones within the last 12 months
6. Known active tuberculosis within the last 12 months
7. Known sarcoidosis within the last 12 months
8. Pregnant or lactating
9. Known hypersensitivity to the trial drug or excipient
10. Medical team deem it not suitable to include patient
11. Known prisoner in the custody of HM prison or probation service

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Eligibility continued

- **Must be confirmed by a medically qualified doctor**
- If inclusion criteria 1-3 are met and none of the exclusion criteria are met, the patient will be considered provisionally eligible. **Written informed consent** will be gained for the trial and a screening blood sample obtained by:
  - A blood sample of approximately 5-10 ml taken from the patient (preferably from an existing line)
  - Alternatively, a vitamin D test added to a routine clinical sample already taken on the same day

Only patients who meet the threshold of 25(OH)D ≤12ng/ml (30nmol/L) will be eligible to continue in the trial.

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Consent

- Patients will, by default be critically ill and due to the effects of sedation, infection, delirium and mechanical ventilation may lack capacity to consent for themselves
- Where patients lack capacity to consent for themselves, consent will be sought from a legal representative
- Patient, personal legal and professional legal consent can be obtained
- Written informed consent must be obtained before performing any trial related procedure

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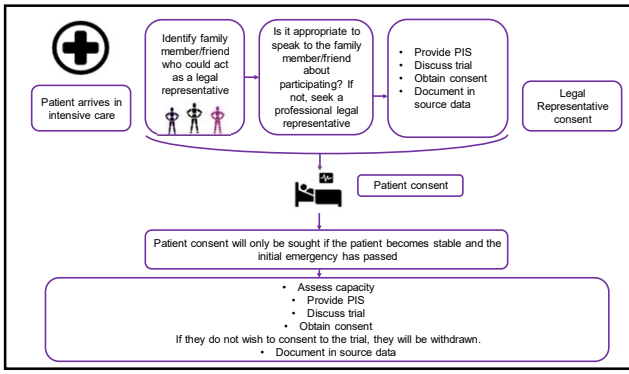

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Consent continued

- Ensure the latest approved versions of the VITDALIZE UK Information Sheets and Informed Consent Forms are used (refer to version control documents).
- Informed consent and ongoing willingness to continue at each visit should always be documented in the medical notes.
  - Where consent is obtained on the same day that the trial related assessments are due to start, a note should be made of the time the consent was obtained and what time the procedures started.

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Consent continued

A copy of the **signed** informed consent form(s) will be given to the **patient or the legal representative**

The original signed form(s) will be retained at the **study site** in the **Investigator Site File** and a copy placed in the **medical notes**.

With the patients/ legal representatives' **consent,** the participants **General Practitioner** (GP) should be informed on discharge – **GP letter**.

Copies of all consent forms will also be sent to the **VITDALIZE UK** Trial Office **via secure method**.

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Randomisation

To randomise a patient into the trial once informed consent has been received and eligibility has been confirmed:

1. Create a new patient using the eCRF Clincase (https://edc.medunigraz.at/clincase/app) to provide a patient trial number (this is needed to complete randomisation)
2. Use the database 'randomizer' (www.randomizer.at/random/login) using the patient trial number, sex and site ID
3. This will then provide the identity code for the trial medication

A confirmatory email will be sent to the randomising user
The user should forward the confirmatory e-mail to any other appropriate site staff, including pharmacy staff

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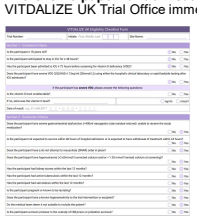
Randomisation

- Please refer to the **randomisation worksheet, flowchart and protocol** when randomising patients into VITDALIZE UK
- **There is no paper randomisation** - if the randomisation system is not working contact the VITDALIZE UK Trial Office immediately



Before randomising the patient into the trial:
- Confirm the patient has severe VDD
- Complete the eligibility checklist CRF (send copy to the VITDALIZE UK Trial Office)

In the event of delays…
- If there has been a >24-hour delay since eligibility was confirmed, eligibility must be re-assessed and eligibility checklist completed prior to randomisation

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Keep a log

- Keep a log of recruited patients on the VITDALIZE UK Patient and Recruitment Log (this is for your record)
- Maintain the VITDALIZE UK Screening/Enrolment Log of patients screened and enrolled (this should be available to be sent to the VITDALIZE UK Trial Office upon request)
- The VITDALIZE Screening/Enrolment Log will be used as a way to review payments for patients

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Trial arms

- Randomisation will be done in a 1:1 ratio stratified by centre and sex

Intervention

Single loading dose (oral/enteral) vitamin D3 (540,000IU cholecalciferol, oleovit™ dissolved in 37.5ml of medium chain triglycerides (MCT) followed by 4000IU daily (10 drops) for 90 days

Control

Placebo, identical treatment regime of 37.5ml MCT followed by 10 drops MCT daily for 90 days

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Trial interventions

- The trial medication is provided by Fresenius Kabi Austria GmbH
- Labelling, filling, packing and distribution of the trial medication will be provided by certified pharmacy Landesapotheke, Müllner Hauptstraße 50 5020 Salzburg
- Can be stored up to 25 ˚C and kept out of direct sunlight
- Temperature monitoring in line with local practice, with evidence available to ensure appropriate storage.
- Shelf life between 1-2 years – expiry date is on Annex-13 label
- SmPC in the ISF and Pharmacy File

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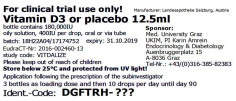
Trial interventions

- Will arrive as a pack of 20-28 boxes (130 x 45 x 68mm boxes) depending on availability
- Each box contains 5 identical bottles labelled with the annex 13 label
- When the interventions arrive the proof of receipt form should be completed to ensure the interventions have not been damaged in transit (a copy is then sent to the VITDALIZE UK Trial Office)
- Add medication to the VITDALIZE UK Accountability Log
- When a patient is randomised, the box with the identity code will be dispensed to the ICU for the patient using the accountability and dispensing log



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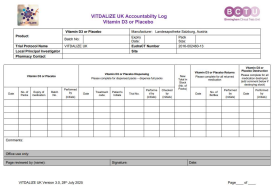
Trial interventions

- Log all received, dispensed, returned, and destroyed trial interventions on the VITDALIZE UK Accountability log
- Complete the VITDALIZE UK dispensing log for each participant dispensed intervention
- Trial interventions can only be destroyed if the VITDALIZE UK Trial Office has given appropriate approval in writing.



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Trial interventions - things to note

- If there has been a >24-hour delay since eligibility was confirmed, eligibility must be re-assessed prior to the patient receiving the loading dose
- Trial intervention can be given orally or through the patient's feeding tube
- Up to 800IU/day concomitant vitamin D supplementation is permitted

- If misplaced, patients will not receive any further intervention
  - Research team to ensure remaining trial intervention provided to patient upon discharge
- Accountability of any returns performed by research team then transferred to pharmacy.

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Schedule of assessment

Day of study medication loading dose; start for the calculation of time dependant outcome data

ASSESSMENT	Screening Day -3 to Day 2	Enrolment/ Baseline Day 0	Begin Daily Dose Day 1	Follow-Up Day 8	Follow-Up Day 12	Follow-Up Day 28	Follow-Up Day 90	Follow-Up Month 12
Time window (days)				±2	±2	±4	±14	±30
ANCHOR[1]	X							
Eligibility assessment	X	X						
Informed consent	X	X						
Randomisation		X						
Baseline demographics		X						
SAPS III		X						
TISS 28		X						
Charlson comorbidity index		X						
Adverse events								
Mortality[1]				X		X[2]	X	X
Serum calcium	X	X		X		X[2]		
Falls							X	
Fractures							X	
New episodes of nephrolithiasis							X	
Number of organ failures[1]		X		X				
Infections requiring antibiotics[1]							X	
Hospital and ICU readmission[1]							X	
Intervention								
Loading dose 540,000 IU or matched placebo		X						
Daily dose 4,000 IU or matched placebo			X	X	X	X	X	
Outcome measures								
SOFA		X		X				
qSOFA		X						
Discharge destination							X	
Katz Activity of Daily Living		X					X	
NHS digital, ONS/HES data								X
Vitamin D metabolic profiling (optional research)		X[3]		X[3]	X[3]			
UK specific outcomes								
Health related quality of life (proxy EQ-5D-5L)		X[3,4]				X[3,4]	X[3,4]	X[3,4]
Health related quality of life (EQ-5D-5L)		X[3]				X[3]	X[3]	X[3]
Disability assessment (proxy WHODAS 2.0)		X[3,4]				X[3,4]	X[3,4]	X[3,4]
Disability assessment (WHODAS 2.0)		X[3]				X[3]	X[3]	X[3]
Health economics questionnaire						X[3]	X[3]	X[3]

[1] Outcome measure
[2] Primary outcome
[3] If still an inpatient
[4] If patient recruited pre-SAS implementation and consents to the sub-study
[5] If patient recruited pre-SAS implementation
[6] To be used if the patient does not have capacity

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Data Management

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Data management

- Data for the VITDALIZE UK Trial will be entered on 2 databases

Main trial outcomes	**UK specific data**
Collected on the eCRF, completed by the research staff at site.	Collected on paper CRFs by the research staff at site and entered into the UK database by the VITDALIZE UK Trial Office.

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Data management for eCRF

- Research staff will be provided with unique log-in usernames and passwords for the online system
- The system will include data validations that will be highlighted if there are erroneous data
- **VITDALIZE UK worksheets and work instructions are available to assist with data entry of data on eCRF – we recommend that you use these.**
- If the VITDALIZE UK worksheets are used they will be classed as source data

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Data management for paper CRF

- Research staff will complete the paper CRFs and send a copy securely to the VITDALIZE UK Trial Office.
- File original paper CRFs securely in your ISF.
- Ensure CRFs are identifiable using trial number and initials.
- Corrections must be initialled and dated.

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CRF Timeline

Pre-randomisation	Baseline (Day 0)	Day 5	Day 28	Day 90	1 year
Eligibility Checklist Form	Visit 1 (day 0) eCRF/ worksheet	Visit 2 (day 5) eCRF/ Worksheet	Visit 3 (day 28) eCRF/ Worksheet	Visit 4 (day 90) eCRF/ Worksheet	Visit 5 (1 year) eCRF/ Worksheet
Informed Consent	WHODAS 2.0*		WHODAS 2.0*	WHODAS 2.0*	WHODAS 2.0*
Contact Details Form	EQ-5D-5L*		EQ-5D-5L*	EQ-5D-5L*	EQ-5D-5L*
			Health economics CRF*	Health economics CRF*	Health economics CRF*
					Study discontinuation eCRF/ worksheet

If applicable. Only applicable if patient recruited pre substantial amendment 5 (SA5) implementation; Not collected for patients recruited post SA5 implementation.

Other forms without a specific timepoint:

- Discharge information eCRF/worksheet: once discharged from primary ICU and ward
- Study discontinuation eCRF/worksheet
- Change of status CRF (UK; paper)
- Adverse events eCRF/worksheet
- SAE form eCRF
- SAE form (UK; paper)
- Pregnancy form (UK; paper)

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Data entry

eCRF (remote) data entry	Paper CRF data entry
• Baseline – Day 0 • Day 5 • Day 28 • Day 90 • 1 Year • Discharge information • Study discontinuation • Adverse event reporting • SAE form (international)	• Eligibility checklist form • Informed consent form • Contact details form • Questionnaires (EQ-5D-5L; WHODAS 2.0)* • Change of status form • Health economics questionnaire form* • SAE form • Pregnancy form ***If applicable. Only applicable if patient recruited pre substantial amendment 5 (SA5) implementation; Not collected for patients recruited post SA5 implementation.***

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Study discontinuation & change of status

The **eCRF study discontinuation** form will need to be completed for the following reasons:

- Completed study alive
- Death
- Lost to follow up
- Full withdrawal

In addition, the ***paper change of status form*** will require completion if the patient has:

- Died
- Discontinued IMP early
- Withdrawn (all types of withdrawal)

Send a copy to the VITDALIZE UK Trial Office

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Patient withdrawal

Types:

The patient would like to withdraw from trial treatment, but is willing to be followed up in accordance with the schedule of assessments and via any central UK NHS bodies for long-term outcomes (i.e. the patient has agreed that data can be collected and used in the trial analysis)

The patient would like to withdraw from trial treatment and does not wish to attend trial visits in accordance with the schedule of assessments but is willing to be followed up at standard clinic visits and via any central UK NHS bodies for long-term outcomes (i.e. the patient has agreed that data can be collected at standard clinic visits and used in the trial analysis, including data collected as part of long-term outcomes)

The patient would like to withdraw from trial treatment and is not willing to be followed up in any way for the purposes of the trial and for no further data to be collected (i.e. only data collected prior to the withdrawal can be used in the trial analysis)

The details of withdrawal (date, reason, and type of withdrawal) should be clearly documented in the source data.

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Data queries

VITDALIZE UK uses a Data Clarification Form (DCF) process:

Paper CRF data queries	eCRF data queries
• The VITDALIZE UK Trial Office at BCTU will to generate data queries to sites in batches • DCFs should be completed by members of the site staff who are on the delegation log and have been assigned the roles of CRF completion and correction • Sites will continue to receive reminders about outstanding DCFs approximately every 2 weeks until resolution	• The Sponsor will review data held on the eCRF and produce data queries • Data queries will be sent to the VITDALIZE UK Trial Office every 6 months • The VITDALIZE UK Trial Office will distribute these to sites to action

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Pharmacovigilance

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Definitions

Adverse event

Any untoward medical occurrence in a patient or clinical trial participant administered a medicinal product which does not necessarily have a causal relationship with this treatment

Adverse reaction

Any untoward response in a participant to an investigational medicinal product which is related to any dose administered to that participant.

Relatedness must be determined by medically qualified personnel.

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Definitions - serious

Any adverse event or adverse reaction that:

- Is life-threatening
- Results in death
- Requires hospitalisation or prolongs existing hospitalisation
- Results in persistent or significant disability or incapacity
- Consists of a congenital anomaly or birth defect

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Definitions - unexpected

An adverse reaction, the nature and severity of which is not consistent with the information about the medicinal product set out in the SmPC or IB for that product.

For the VITDALIZE UK Trial, the SmPC will be provided for vitamin D3 and will be used to assess expectedness.

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Reporting

- The reporting period is from randomisation until 15 days after the last IMP administration
- The Investigator will assess the severity, seriousness and causality (relatedness) of all AEs experienced by the patient.
- All AEs should be assessed during follow-up and recorded in the patient's medical notes
  - Data on AEs are collected on the eCRF
  - Only AEs associated with the negative effects of the IMP to be reported in the eCRF:
    - Kidney stones
    - Falls
    - Hypercalcemia
    - Fractures
    - Other – associated with study medication

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Reporting

SAEs that are excluded from reporting

- At whatever time they occur during an individual's participation the following are 'protocol exempt' SAEs:
  - Events related to the patient's pre-existing condition(s)
- All events which meet the definition of 'serious' must be recorded in the patient's medical notes, including causality, throughout the patient's time on the trial.

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Reporting

SAEs that do not require expedited (immediate) reporting

Event	CRF
Mortality[1]	Study Discontinuation Form, Change of Status Form and SAE Form[4] (if applicable)
Change in organ dysfunction (number of organ failures)	Day 0; Day 5 Form; Adverse Events Form[5]
Hypercalcaemia[2]	Adverse Events Form[5]
New episodes of nephrolithiasis[3]	Adverse Events Form[5]
Falls and fractures	Adverse Events Form[5]
Infections requiring antibiotics treatment	Day 90 Form

[1] Mortality due to a pre-existing condition requires documenting on the Study Discontinuation Form located on the eCRF and Change of Status Form
[2] Where persistent hypercalcemia is present, it is a clinical recommendation for a parathyroid hormone (PTH) test to be performed before continuing with the trial medication
[3] Decrease/increase in kidney function, specifically CKD 4 (eGFR <30mL/min/1.73m^2)
[4] SAE form to be completed if there is a causal relationship to intervention
[5] Please note that the Adverse Events Form is **not** a SAE Form

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Reporting

Events that require expedited (immediate) reporting

- The research team will report all other SAEs that are not previously defined in an expedited manner, **within 24 hours of becoming aware of event.**
- The research team are required to report expedited SAEs using both the:
  - eCRF (minimum dataset)
  - Paper SAE Form
- If mortality is deemed to have a causal relationship with the intervention it should be reported in an expedited manner.

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Reporting SAEs

To report SAEs the following is required:

1. Complete the UK SAE paper form and send to the VITDALIZE UK Trial Office
2. Complete the adverse events form on the eCRF
3. Complete the paper SAE form for the eCRF and send to the VITDALIZE UK Trial Office

Report both SAE forms to the VITDALIZE UK Trial Office by:

- Email (vitdalize@trials.bham.ac.uk)
- In all cases, please either call the VITDALIZE UK Trial Office (0121 414 7943) or email to inform that a SAE is expected

We recommend that the SAE work instruction is used to assist with the reporting procedure

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Pregnancy

If a patient becomes pregnant during the SAE reporting period:

- Advise patient to stop taking their trial medication.
- Complete a Pregnancy Notification Form and return to the VITDALIZE UK Trials Office.
- If applicable, report SAE to the VITDALIZE UK Trials Office.

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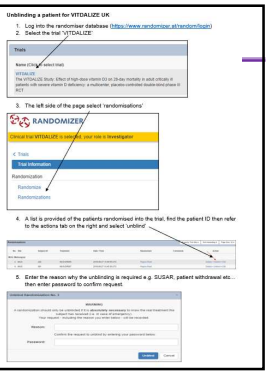
Unblinding

- Should any SAEs occur, the management and care of the patient will be initiated as though they're on high dose vitamin D.
- Where events are considered serious, unexpected and possibly/probably/definitely related an emergency unblind can be performed and VITDALIZE UK Trial Office should be notified.
- Requests for non-emergency unblinding should be made to the VITDALIZE UK Trial Office.
- **Trial-specific unblinding work instructions in place**



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What needs to be urgently reported?

All SUSARs and expedited SAEs <u>must</u> be reported to BCTU within 24 hours of the site being made aware of the event

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Quality Control & Assurance

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Monitoring and audit

Central Monitoring

Including consent checks, data checks (data quality, timeliness), and checking balance of allocations

On-Site Monitoring

Additional onsite visits may be triggered, e.g., poor data quality, deviations

Including source data verification

Inspections from MHRA and/or audits from Trust R&D Department

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Source Data

Source data: all information in the original records (clinical findings, observations, or other trial activities) necessary for the reconstruction and evaluation of the trial

- Needs to be accessible and maintained

Data	Source
Patient/Proxy Reported Data (EQ-5D-5L; WHODAS 2.0)	Completed paper form.
Laboratory results	Original lab report (which may be electronic). In situations where worksheets are used, these will be source data.
Clinical event data	Original clinical annotation. In situations where worksheets are used, these will be source data.
Health economics data	Completed paper Health Economics CRF.
Recruitment	Original record of the randomisation, held on the Medical University of Graz eCRF servers.
Withdrawal	Where a participant expresses a wish to withdraw, the conversation must be recorded in the source data.

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Deviations and Potential Serious Breaches

- Protocol deviations should be reported to the VITDALZE UK Trial Office

Serious Breaches:

- Sites must notify the VITDALIZE UK Trial Office of any suspected trial-related serious breach of GCP and/or the trial protocol as soon as it becomes aware of them
- Sites must provide sufficient information to report the breach and engage with undertaking any CAPA

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Delegation log

- PI has overall responsibility for study conduct at each site
  - PIs can delegate certain study-related tasks to sub-investigators, clinicians, research nurses, and any other study related staff
  - It is essential that there is clear and documented evidence of PI oversight and involvement in the trial
- Delegation log must be **signed and dated** by all staff involved in the trial and kept current throughout the trial.
- BCTU must also be in receipt of **signed and dated CVs, GCP certificates, and study training logs** for all staff listed on the delegation log

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Site file

- BCTU will provide each site with an 'Investigator Site File' containing the essential document set
- Essential documents:
  - Help you understand the project's purpose and methodology and record relevant approvals
  - Provide evidence that trial staff are qualified, trained, and authorised to work on the trial
  - Record approvals and substantial amendments
  - Document SAEs
  - Record the trial's findings, dissemination and archiving arrangements

ISFs should be checked for completion upon receipt, always kept up to date by site staff (e.g. CVs, GCPs, training logs/document version control/ ICFs / CRFs / SAEs / File notes etc.), and available for monitoring, inspection, or audit.

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Archiving

All essential trial documentation and source documents (e.g. signed ICFs, ISFs, Pharmacy Files, patients' hospital notes, copies of CRFs etc.) at site must be securely retained for **at least 25 years**.

No documents should be destroyed without prior approval from the VITDALIZE UK Trial Office.

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Associate PI scheme

- VITDALIZE UK is registered to the NIHR associate PI scheme and is aimed at:
  - Healthcare professional who want to gain knowledge of what it means to deliver an NIHR portfolio trial.
  - Able to commit to six months of working on a study registered on the Scheme at their local site.
  - Do not currently work in research and would like the opportunity to gain experience and mentorship from a local study PI.
- Further details on how to register as an associate PI can be found on the NIHR website:
  - https://www.nihr.ac.uk/health-and-care-professionals/career-development/associate-principal-investigator-scheme.htm

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Contact details

- Email: vitdalize@trials.bham.ac.uk
- Tel: +44 (0)121 414 7943
- Postal Address: **VITDALIZE UK** Trial Office, Birmingham Clinical Trials Unit (BCTU), College of Medical and Dental Sciences Public Health Building, University of Birmingham, Edgbaston, Birmingham, B15 2TT
- Trial website (data entry): https://edc.medunigraz.at/clincase/app
- Randomisation website: https://www.randomizer.at/random/login
- VITDALIZE UK website: VITDALIZE UK - University of Birmingham
- Confirm training: https://redcap.link/VITDALIZETrainingLog

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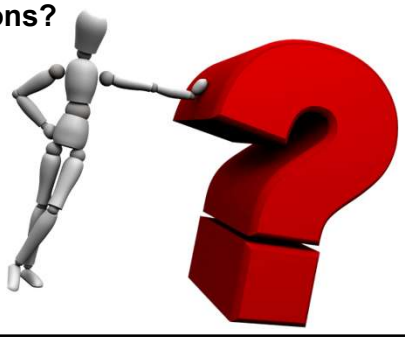
Questions?



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