



SED-CARE

TEMP-CARE

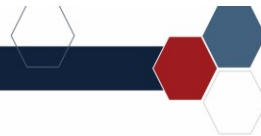
MAP-CARE



Sedation Temperature and Pressure after Cardiac Arrest and Resuscitation



Medical Research
Future Fund



hrc nz





CONSENT, DATA ENTRY, eCRF & REMOTE MONITORING

Frances Bass: ICU Research Manager (RNSH) &
Senior Project Manager (TGI), Australia

Dr Josef Dankiewicz: Cardiologist, Lund



consent

● **n.** permission. ● **v.** give permission.

➤ agree to do something. – PHRASES

informed consent permission granted in the knowledge of the possible consequences.

– ORIGIN **ME:** from OFr. *consente* (n.), *consentir* (v.), from L. *consentire*, from *con-* ‘together’ + *sentire* ‘feel’.



Informed Consent Model

x Consent from participant PRIOR to randomisation will NOT be possible

✓ Consent from Legally Authorised Representative (LAR), Person Responsible (PR)/ Substitute Decision Maker (SDM)/Medial Treatment Decision Maker (MTDM) PRIOR to randomisation

- Whenever possible consent will be obtained from a LAR/PR/SDM/MTDM prior to randomisation

✓ Inclusion without prior consent with option to continue or withdraw

- Patients enrolled into the trial without prior consent, the participant or LAH/PR/SDM/MTDM informed about participation in study as soon as possible and given the option of consent to continue in the trial, or to withdraw from the trial



Who Obtains Consent?

- ICH-GCP: investigator's responsibility
- The investigator, or a person designated by the investigator, should fully inform the patient or LAR
- Investigator or designee (Co-PI, Sub-PI, RC.)
- Qualified, trained on the study protocol, consenting
- Comply with local ethical and regulatory requirement
- Any person obtaining consent throughout the study must be listed on the Site Signature & Delegation Log

How should consent be administered?

- Timing: before participation
- Environment: private, confidential dialogue can take place
- Fully inform all pertinent aspects of the trial
 - Orally and EC approved information sheet
- Non-technical and practical language
- Do not use language
 - to coerce or unduly influence to participate
 - that causes/appears to waive any legal rights or appear to release the investigator, institution, sponsor or their agents from liability for negligence
- Provide ample time and opportunity to inquire about the details of the trial and answer questions



What information should be provided to participants?

- Voluntary, can refuse, withdraw anytime
- Access to participant original medical records for verification, ensuring confidentiality, by monitors, auditor, ECs and reg. authorities
- Participants identify will be kept confidentiality
- If new information becomes available that is relevant to participation it will be provided in a timely manner
- Payments for participation, expenses to the participant



What information should be provided to participants?

- Contact details
 - for further information and the rights of the participant
 - event of trial-related injury
- Circumstances and/or reasons under which the subject's participation in the trial may be terminated
- Expected duration of participation in the trial
- Approximate number of participants involved in the trial



Consent Documentation

- The Participant or LAR/PR/SDM/MTDM and the person obtaining consent must sign and date the consent form
- All signed forms must be retained for 15 years
- Original signed consent form (and information sheet) is kept with the study file,
 - One full copy filed in patient's medical records
 - One full copy given to patient/PR/SDM/MTDM
- The consent process should be documented in the patient's medical record
- All consents will be reviewed at Site Monitoring Visits




Withdrawal of Consent

- The participant and/or their LAR/PR/SDM/MTDM may withdraw their consent to participate in the study at any time
- Please seek permission (with discretion) to
 - use all trial data
 - use trial data collected up to date of withdrawal
 - access medical record to obtain health information
 - contact participant at 30-days, 6 and 12-months to obtain health information
 - complete follow-up questionnaires by telephone or face-to-face visit to obtain health information
- Complete the “Participant Withdrawal of Participation” found on the last page of the Information Sheet and Consent Form
- Document in the patient’s medical records and study file





Data Collection

- Data collected up to 12 months post-enrolment, or to death (whichever occurs first)
- eCRF built using Spinnaker
- Keep your login ID and password information confidential
- All data definitions and explanations are explained thoroughly within the database by selecting the information button 
- There is not a separate data dictionary or study completion manual



Database & eCRF



<https://stepcare.spinnakersoftware.com>







Database Home Page



Participants

Screening log

Resources

Manage

Monitoring

Reports

Andromeda Infirm...



+ Add participant

14 Participants randomised at 997 - Andromeda Infirmary

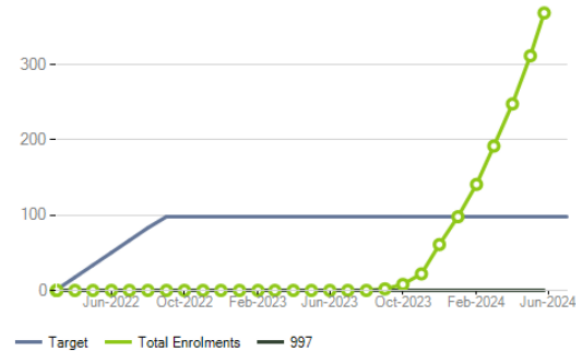
Participant Study Number

Find participant

Participant	Age	Sex	Initials	Day	Randomised
9970014	25	Male	TAB	45	11-Apr-2024
9970013	25	Male	ABCD	46	10-Apr-2024
9970012	58	Male	JTU	108	08-Feb-2024
9970011		Male		206	02-Nov-2023
9970010	36	Male	JUO	220	19-Oct-2023
9970009	44	Male	ATT	223	16-Oct-2023
9970008	56	Female	LOP	243	26-Sep-2023
9970007	47	Female	EEN	250	19-Sep-2023
9970006	39	Female		256	14-Sep-2023
9970005	39	Male	RRR	256	13-Sep-2023
9970004	59	Male	DGU	256	13-Sep-2023
9970003	23	Male	NNN	270	30-Aug-2023
9970002	19	Male	HJK	283	17-Aug-2023
9970001	34	Male	MOB	293	07-Aug-2023

Alerts at 997 - Andromeda Infirmary

369 enrolments in the STEPcare Trial
14 enrolments at 997 - Andromeda Infirmary



Randomising & Screening Patients



Participants

Screening log

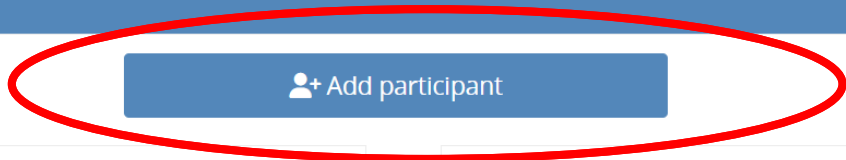
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Andromeda Infirm...



+ Add participant

14 Participants randomised at 997 - Andromeda Infirmary

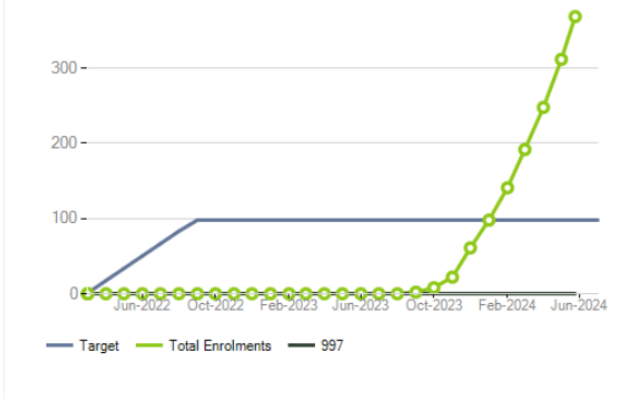
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Alerts at 997 - Andromeda Infirmary

369 enrolments in the STEPcare Trial
14 enrolments at 997 - Andromeda Infirmary





Eligibility

Patient details

Eligibility criteria

Consent

Result

Test site only - Do Not enter real patient details

Participant details

Participant initials ⓘ

Initials starting with the first name e.g. James Tiberius Kirk (JTK)

Unknown at this time

Date of birth ⓘ

 e.g. 01-Jun-1965

Unknown at this time, presumed to be over 18

Sex at birth ⓘ

Date and time of Return of Spontaneous Circulation (ROSC) ⓘ

Current time must be >20 minutes and <240 minutes after ROSC.

 : : 24 Hour clock

Next

[Cancel](#)



Patient details

Eligibility criteria

Best Interests

Consent

Result

Eligibility criteria

Arrest location ⁱ

Out-of-hospital is defined as a patient not currently admitted in the hospital

In-hospital

Out-of-hospital

Arrest Cause ⁱ

Please select the most probable cause of arrest as judged at the time of randomisation. If VT/VF and no other information choose arrhythmia not related to acute ischemia.

Cardiac

Non-cardiac

Trauma/Bleeding

Intracranial bleed

Unconscious ⁱ

Is the patient unconscious or intubated and sedated due to agitation

Yes

No

Is the patient eligible for intensive care without restrictions or limitations ⁱ

Yes

No

Is the patient on ECMO ⁱ

Yes

No

Is the patient pregnant ⁱ

Yes

No

Previously randomised in the STEPCARE trial

Yes

No

Next

[Cancel](#)



Patient details

Eligibility criteria

Best Interests

Consent

Result

Consent

Are all local consent requirements met i

Yes

No

Perceived prognosis - for research purposes

Does not impact randomisation and patient care

Do you (physician randomising or physician in-charge) think this patient will have a good neurological outcome in 6 months



- Yes - I, the physician randomising or physician in-charge, think this patient will have a good neurological outcome in 6 months
- No - I, the physician randomising or physician in-charge, do not think this patient will have a good neurological outcome in 6 months
- I am not a physician and the physician in charge is not available to answer this question right now

Next

[Cancel](#)



This patient is eligible and will be randomised

Confirm

Edit Eligibility

No, add to screening log only

Patient details

Eligibility criteria

Best Interests

Consent

Result

Randomising a Patient



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Andromeda Infirm...



Find Participant

Eligibility



Eligibility

9970014

Randomised 11-Apr-2024
10:59

Patient Summary

Patient details

Eligibility criteria

Best Interests

Consent

Result

Randomisation complete for patient 9970014

Print

Patient is randomised in the STEPCARE-trial at Andromeda Infirmary

The interventions should be started as soon as possible

Randomised to:

Sedation: Continuous sedation for 36 hours

Temperature: Fever management without a feedback-controlled device

Blood pressure: A mean arterial pressure target of >85mmHg

▶ Patient details

Patient initials:	TAB	Patient study no:	9970014
Date of birth:	17-Feb-1999	Age at randomisation:	25
Sex at birth:	Male	ROSC:	11-Apr-2024 08:00
Randomised to database:	11-Apr-2024 10:59	ROSC to randomisation:	179 mins

▶ Best interests statement

Best interests confirmed by team

▶ Person randomising

Anna Tippett

[Patient Summary](#)

Patient Summary



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Andromeda Infirm...



Find Participant

Eligibility



9970014

Randomised 11-Apr-2024
10:59

✓ Summary

✓ Randomisation

? Consent

? Key Baseline

X Baseline

? Hourly Observations

X Neuroprognostication

X Interventions

X Discharge

X Vital Status

X Day 30

X Complications

Participant 9970014

Locked status: Open

Monitoring status: Not Monitored

Participant 9970014

Randomised 11-Apr-2024 10:59

Initials TAB

Date of birth 17-Feb-1999

Age at randomisation 25

Sex at birth Male

ROSC 11-Apr-2024 08:00

Notes

Edit participant

[uSAE +](#)

No uSAE

[Protocol deviations +](#)

No protocol deviations

[Change Log](#)

Table	Type	Date	User
HourlyObs	Insert	23 May	Frances Bass
Consent	Insert	24 April	Josef Dankiewicz
HourlyObs	Insert	16 April	Anna Tippet
KeyBaseline	Insert	11 April	Anna Tippet
... more changes			

Hourly Observations



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Find Participant

Eligibility



9970014

Randomised 11 Apr 2024

10:59

✓ Summary

✓ Randomisation

? Consent

? Key Baseline

X Baseline

? Hourly Observations

X Neuroprognostication

X Interventions

X Discharge

X Vital Status

X Day 30

X Complications

Hourly observations for participant 9970014

Enter the data for each time, or where data are not available, enter data from the closest time where they were available (if there are no new data since the prior time point, leave the field blank)

	End of hour	Time	Date	Measurements	Temperature	MAP	RASS
X	0	11 am	11 Apr				
X	2	1 pm	11 Apr				
X	4	3 pm	11 Apr				
X	6	5 pm	11 Apr				
?	8	7 pm	11 Apr	✓	ND	78.0	
X	12	11 pm	11 Apr				
X	14	1 am	12 Apr				
X	16	3 am	12 Apr				
X	18	5 am	12 Apr				
X	20	7 am	12 Apr				
X	22	9 am	12 Apr				
X	24	11 am	12 Apr				
X	28	3 pm	12 Apr				
X	32	7 pm	12 Apr				
X	36	11 pm	12 Apr				
X	40	3 am	13 Apr				
X	48	11 am	13 Apr				
X	56	7 pm	13 Apr				
X	72	11 am	14 Apr				
X	96	11 am	15 Apr				
?	120	11 am	16 Apr	✓			



Protocol Deviations

- Types of Protocol Deviation's
 - Enrolment of ineligible patient
 - Failure to comply with allocated temperature management strategy
 - Failure to comply with allocated blood pressure management strategy
 - Failure to comply with allocated sedation management strategy
 - Other
- Document one Protocol Deviation per PD form
- Enter Protocol Deviation CRF onto the database ASAP
- Describe the deviation and corrective action taken



Protocol Deviations



9970009

Randomised 16-Oct-2023
13:48

✓ Summary

Participant 9970009

Locked status: Open

Monitoring status: Not Monitored

Participant 9970009

Randomised 16-Oct-2023 13:48

[uSAE +](#)

No uSAE

[Protocol deviations +](#)

No protocol deviations

[Change Log](#)

... more changes



9970009

Randomised 16-Oct-2023
13:48

Participant 9970009

Locked status: Open

Monitoring status: Not Monitored

Participant 9970009

Randomised 16-Oct-2023 13:48

[uSAE +](#)

No uSAE

[Protocol deviations +](#)

ID	Onset date
----	------------

1	27-Aug-2023
---	-----------------------------

Protocol Deviations

Protocol Deviation for participant 9970009

Nature of protocol deviation

Date and time of deviation ⓘ dd--- : : 24 Hour clock

Type of deviation:

- Enrolment of ineligible patient
- Failure to comply with allocated temperature management strategy for reasons not permitted in the protocol
- Failure to comply with allocated blood pressure management strategy for reasons not permitted in the protocol
- Failure to comply with allocated sedation management strategy for reasons not permitted in the protocol
- Other

Please describe the deviation:

Please describe any corrective actions that were taken in reaction to the protocol deviation:

Add Protocol deviation

or [Cancel](#)

Complications – Safety Events



Participants

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Andromeda Infirm...



Find Participant

Eligibility



9970012

Randomised 08-Feb-2024
09:26

✓ Summary

✓ Randomisation

✗ Consent

✗ Key Baseline

✗ Baseline

✗ Hourly Observations

✗ Neuroprognostication

✗ Interventions

✗ Discharge

✗ Vital Status

✗ Day 30

✗ **Complications**

Complications patient 9970012

Infectious Complications in the ICU

Did the patient develop sepsis
According to Sepsis III definition

Did the patient develop pneumonia

Bleeding

Did the patient experience bleeding

Arrhythmic Complications in the ICU

Did the patient have a recurrent cardiac arrest (defibrillation or chest compressions)

Other arrhythmia requiring cardioversion, an anti-arrhythmic drug, or temporary pacing

Venous thromboembolism in the ICU

Deep Vein Thrombosis (DVT) or Pulmonary Embolism in the ICU

Ischemic complication

Mesenteric ischemia

Limb ischemia


Digital necrosis

Sedation Complications

Unplanned extubation

Unexpected Serious Adverse Events



9970009
Randomised 16-Oct-2023
13:48

✓ Summary

Participant 9970009
Locked status: Open
Monitoring status: Not Monitored

Participant 9970009


Randomised 16-Oct-2023 13:48

[uSAE +](#)
No uSAE

[Protocol deviations +](#)
No protocol deviations

[Change Log](#)
... more changes





9970009
Randomised 16-Oct-2023
13:48

/ Summary

Participant 9970009
Locked status: Open
Monitoring status: Not Monitored

Participant 9970009

Randomised 16-Oct-2023 13:48

[uSAE +](#)

ID	Onset date	Outcome
1	16-Oct-2023	Event resolved with sequelae

[Protocol deviations +](#)

ID	Onset date
1	27-Aug-2023

Unexpected Serious Adverse Events

uSAE for participant 9970009

▶ Unexpected serious adverse event

Has there been an unexpected serious adverse event that:

- caused death or
- was life threatening or
- may result in significant disability

AND

- which is NOT expected in a critical ill patient

Yes

No

Add uSAE

or [Cancel](#)

Unexpected Serious Adverse Events

uSAE for participant 9970009

Unexpected serious adverse event

Has there been an unexpected serious adverse event that:

 Yes No

- caused death or
 - was life threatening or
 - may result in significant disability
- AND
- which is NOT expected in a critical ill patient

Date of event

Please describe the event

Was the event related to one of the interventions

What was the outcome

or [Cancel](#)



eCRF test accounts

Test site: <https://stepcare-stage.spinnakersoftware.com/>

Password: cardiacarrest

User name: Choose the location below corresponding to your time zone.

For investigators and nurses

United Kingdom, Ireland (UTC +00.00)

User name: STEPCAREtest_UK

Sweden, Belgium, Italy, Luxembourg, Norway, Switzerland (UTC +01.00)

User name: STEPCAREtest_SE

Finland, Czech Republic (UTC +02.00)

User name: STEPCAREtest_FI

Saudia Arabia, Kuwait (UTC +03.00)

User name: STEPCAREtest_SA

Singapore (UTC +08.00)

User name: STEPCAREtest_SG

Australia (UTC +10.00)

User name: STEPCAREtest_AU



Safety reporting

- Safety events will be reported during the intensive care unit stay only
- Safety events should be reported within 24 hours from awareness of the event
- The specific safety events will be reported whether they are considered related to the intervention or not
- The relatedness between the trial interventions and the unexpected serious complications should be determined by the local investigator

eCRF feedback



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Andromeda Infirm...



Find Participant

Eligibility



9970014

Randomised 11-Apr-2024
10:59

✓ Summary

✓ Randomisation

? Consent

? Key Baseline

X Baseline

? Hourly Observations

X Neuroprognostication

X Interventions

X Discharge

X Vital Status

X Day 30

X Complications

Participant 9970014

Locked status: Open

Monitoring status: Not Monitored

Participant 9970014

Randomised 11-Apr-2024 10:59

Initials TAB

Date of birth 17-Feb-1999

Age at randomisation 25

Sex at birth Male

ROSC 11-Apr-2024 08:00

Notes

Edit participant

[uSAE +](#)

No uSAE

[Protocol deviations +](#)

No protocol deviations

[Change Log](#)

Table	Type	Date	User
HourlyObs	Insert	23 May	Frances Bass
Consent	Insert	24 April	Josef Dankiewicz
HourlyObs	Insert	16 April	Anna Tippett
KeyBaseline	Insert	11 April	Anna Tippett
... more changes			

Feedback

fbass@georgeinstitute.org.au



Status Board

Group by: Status | Sort by: Date created

New In 7

ID 3803323 • General May 23
• Baseline Form o Physiology and investigations - highest outpatient (not in hospital) creatinine me...
0

ID 3796531 • Bug May 22
Biobank
0

ID 3753141 • General May 14
CONSENT: ? regression bug - can't add correct ethics approval date to consent section
1

ID 3731351 • General May 09
Hello, can we please have an option for not assessed for shivering and not available for non core t...
0

ID 3719909 • General May 07
last given dose of sedative prior to prognostication is 20 min. Its not possible to fill in less tha...
0

Internal 9

ID 3696813 • Bug May 02
Vital status
0

ID 3653143 • Bug Apr 24
Patient can't be dead after 30 days
1

ID 3565791 • Idea Apr 10
ECHO result
0

ID 3491059 • Bug Mar 28
Highest outpatient creatinine
0

ID 3479179 • General Mar 26
For pat. who died before consent could be obtained; How do I answer the question if it's ok to conta...
0

ID 3361434 • General Feb 27
PT SUMMARY | Make ROSC editable from pt summary

Lhotse 12

ID 3710967 • General May 06
NEURO | Add neurological outcome question
0

ID 3701451 • General
OBS | Hour 10
1

ID 3697227 • Bug May 02
OBS | Update core temp range
1

ID 3696941 • Bug May 02
OBS | Update heart rate range
0

ID 3644461 • Bug Apr 23
Server Error when attempting to navigate to DIS
0

ID 3638965
DIS | Extubal pts since las

Staged 0

No feedback in this column

Duplicate tickets 32

ID 3577047 • Bug Apr 12
DIS - Server error when accessing discharge CRF
0

ID 3475475 • General Mar 26
Hourly Obs: reduce the Heart rate lower value to 30 please
0

ID 3389372 • Idea Mar 08
drug usage; Noradrenaline
0

ID 3342625 • Bug Feb 19
biobank
1

ID 3300412 • Bug Jan 31
inspiratory pressure 8 is not possible to report. Change the lower limit to 8?
0

ID 3270622 • Idea Jan 19
Sepsis 3 definition

Matterhorn 16

ID 3787599 • C
CONSENT form withdrawal que
'No' is selected
0

ID 3453965 • C
CON | Logic for
1

ID 3443743 • B
Pt LIST | Full list
1

ID 3434249 • C
INT | Allow to s
data entered
0

ID 3434247 • C
INT | Change fr
decimals
1

ID 3411711 • G





<https://stepcare.org/>



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The STEPCARE (Sedation, Temperature and Pressure after Cardiac Arrest and Resuscitation) trial

Program for the STEPCARE meeting in Helsingborg May 29th

23 May, 2024



The first STEPCARE-patient at Østfold Hospital Kalnes, Norway, is now included!

14 May, 2024

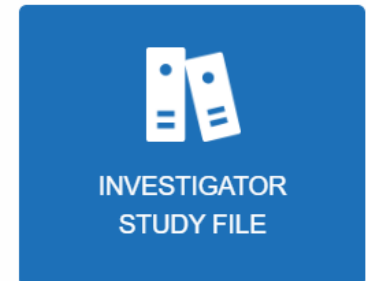
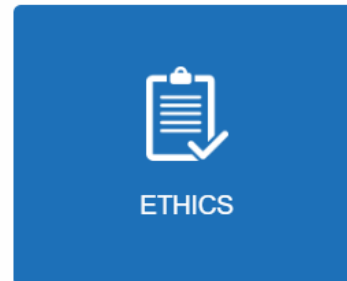
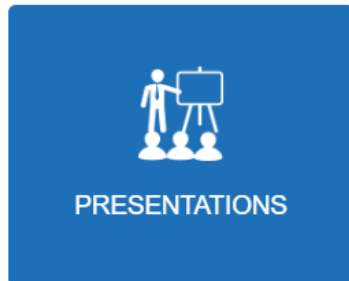
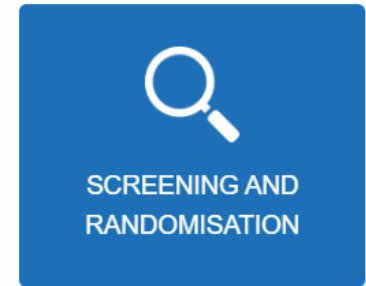
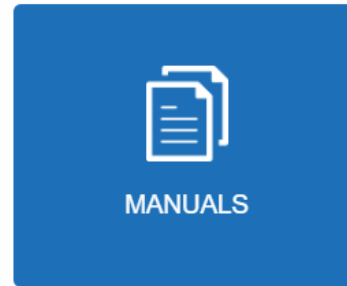
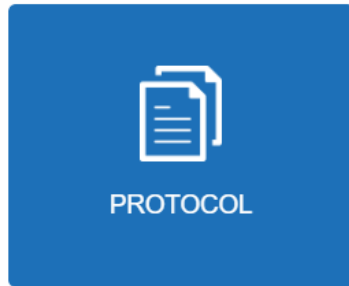


First randomization at Prince Charles Hospital

22 April, 2024



Documents





Monitoring

- The purpose of monitoring is to ensure that the clinical trial is conducted in accordance with the study protocol, GCP and any local regulatory requirements
- Early visits conducted to pick-up any consistent errors and to discuss issues (if any)



Remote Monitoring

Josef to discuss



Source Data Verification

- The purpose of SDV is to document the existence of the patient and substantiate integrity of the study data collected
- A source document is the first place something is recorded i.e. original documents, data and records
- Data collected should be from a source document which can be verified by a study monitor or local/national regulatory authorities.
- Examples of source documents include medical notes (electronic or paper), laboratory results, ambulance chart, ED charts, ward charts, OT charts and other hospital records
- A paper case report form is not a source document

