



CYCLE RCT #142

Plate #001

Visit #000

Patient ID Coded Patient Initials
(site #) (patient type) (patient #)
1=randomized
2=eligible non-randomized
F L

Screening Date
(dd/mm/yyyy)

SCREENING (Form 1)

1. Inclusion Criteria (please tick the appropriate check-box)

1. Patient is ≥ 18 years of age
2. Patient is invasively mechanically ventilated ≤ 4 days
3. Expected additional 2 day ICU stay
4. Ability to ambulate independently (with or without gait aid) pre-hospital
5. ICU length of stay ≤ 7 days

YES NO

Y N
Y N
Y N
Y N
Y N

2. Exclusion Criteria

1. Pre-hospital inability to follow simple commands in local language at baseline
2. Acute conditions impairing ability to receive cycling (e.g., leg fracture)
3. Acute, proven, or suspected central or peripheral neuromuscular weakness (e.g., stroke, Guillian Barre)
4. Temporary pacemaker (internal or external)
5. Expected hospital mortality ≥ 90%
6. Equipment unable to fit patient's body dimensions (i.e., amputation, morbid obesity)
7. Palliative goals of care
8. Pregnancy
9. Specific surgical exclusion as stipulated by surgery team or ICU team

Y(specify)

Y(specify)

Y N
Y N
Y N
Y N
Y N
Y N
Y N
Y N
Y N
Y N

10. Physician declines (i.e., severely impaired skin integrity, unstable in other ways)
(specify) _____

11. Patient already able to march on the spot at time of screening

Y N

12. Cycling Exemption not resolved during 1st 4 days of MV

Y(check all; specify if necessary)

1. Increase in inotropes/vasopressors (2h)
2. Active MI, or unstable/uncontrolled arrhythmia per ICU team
3. MAP <60 or >110 (2h) or out of range for this patient per ICU team
4. HR <40 or >140 (2h)
5. SpO₂ <88% (2h) or out of range for this patient per ICU team
6. Neuromuscular blocker (4h)

7. Severe agitation RASS >2 or SAS >6 or equivalent (2h)
8. Uncontrolled pain
9. Changes in goals to palliative care
10. Other concern (e.g., active haemorrhage, acute peritonitis, new pelvic, groin, or extremity wound precluding cycling, new known or suspected muscle inflammation)
(specify) _____

Y N

3. Study Eligible Non-Randomized Patients (enter into iDataFax)

1. Patient or SDM/ LAR declines consent
2. Patient unable to give consent and no SDM/ LAR identified
3. Physician declines patient or SDM/ LAR to be approached (specify) _____
4. Consent not obtained due to other reason (check ONE box only, for items a through f)

Y N
Y N
Y N
Y N

- FULL PT STAFF
- a. Insufficient PT resources and no CYCLE patients enrolled in ICU
 - b. Insufficient PT resources because CYCLE patient(s) enrolled in ICU
 - c. No PT available (off site, no PT around)
- ↓ PT STAFF
- d. Insufficient PT resources (e.g. randomization on hold → only use after consulting with Methods Centre)
 - e. No RC available (off site, not available to screen)
 - f. Other reason (specify) _____

5. Previously enrolled in this study (previous admit). Prior ID: _____

Y N

4. Patient Status (check ONE box only)

Eligible, non-randomized

Included (go to Randomization Form 2)

5. Who provided consent? (check ONE box only)

Patient SDM/ LAR

6. Who obtained consent? (check ONE box only)

RC Site Investigator ICU MD