



# RAPID

Palliative Care  
Clinical Studies  
Collaborative (PaCCSC)

## Midazolam for Agitation - Baseline

Staff email

Participant ID

Date of Baseline



Now

D-M-Y H:M

Initials of person entering data

### Demographics

Gender

- Male  
 Female

reset

Age

Weight (kg)

Height (cm)

**Primary life limiting illness**

- Advanced metastatic cancer
- End stage renal failure
- Hepatic failure
- Neurodegenerative disease
- AIDS
- Cardiac failure
- Respiratory failure
- Other

reset

**Palliative Care Phase?**

- Stable
- Unstable
- Deteriorating
- Terminal

reset

**1. Stable:** The person's symptoms are adequately controlled by established management. Further interventions to maintain symptom control and quality of life have been planned.

**2. Unstable Phase:** The person experiences the development of a new problem or a rapid increase in the severity of existing problems either of which requires an urgent change in management or emergency treatment

**3. Deteriorating Phase:** The person experiences a gradual worsening of existing symptoms or the development of new but expected problems. These require the application of specific plans of care and regular review but not urgent or emergency treatment.

**4. Terminal Care Phase:** Death is likely in a matter of days and no acute intervention is planned or required.

**Laboratory tests (only if available)**

Serum albumin

International normalised ratio (INR)

C-Reactive Protein (CRP)

Calculated creatinine clearance (CCr) or eGFR

Haemoglobin (Hb)

**Is the patient considered to be:**

- In the last week of life
- Not in the last week of life

reset

### Charlson Comorbidity Index

- Myocardial infarct
- Congestive cardiac failure
- Peripheral vascular disease
- Cerebravascular disease
- Dementia
- Chronic pulmonary disease
- Connective tissue disease
- Ulcer disease
- Mild liver disease
- Diabetes
- Hemiplegia
- Moderate or severe renal disease
- Diabetes with end organ damage
- Any tumour
- Leukaemia
- Lymphoma
- Moderate or severe liver disease
- Metastatic solid tumour
- AIDS

### Australian Modified Karnofsky Performance Scale (AKPS)

- 100 = Normal; no complaints; no evidence of disease
- 90 = Able to carry on normal acitvity; minor signs or symptoms
- 80 = Normal activity with effort; some signs of symptoms or disease.
- 70 = Cares for self; unable to carry on normal activity or to do active work.
- 60 = Requires occasional assistance but is able to care for most of his needs.
- 50 = Requires considerable assistance and frequent medical care.
- 40 = In bed more than 50% of the time.
- 30 = Almost completely bedfast.
- 20 = Totally bedfast and requiring extensive nursing care by professionals and/or family.
- 10 = Comatose or barely rousable.
- 0 = Dead
- Not able to determine

reset

## T0-Baseline - Medication Commencement

**Richmond Agitation-Sedation Scale**

- +4 Combative - violent, immediate danger to staff +/- attempting to get out of bed or chair
- +3 Very agitated - Pulls or removes lines, aggressive +/- attempting to get out of bed or chair
- +2 Agitated - Frequent non-purposeful movement, +/- attempting to get out of bed or chair
- +1 Restless - Occasional non-purposeful movement but movements not aggressive or vigorous
- 0 Alert and calm
- 1 Drowsy - Not fully alert, but has sustained awakening to voice (10 seconds or longer)
- 2 Light sedation - Briefly awakens with eye contact to voice (less than 10 seconds)
- 3 Moderate sedation - Any movement or eye opening to voice (but no eye contact)
- 4 Deep sedation - No response to voice, but any movement or eye opening to stimulation by light touch
- 5 Not rousable - No response to voice or stimulation by light touch

reset

**What dose has been given at this point in time?**

**Motivation to/Purpose in treating?**

- Patient safety
- Family concern
- Staff concern
- Patient symptoms
- Other

**Baseline Toxicity Assessment: Please grade all symptoms accordingly**

- Amnesia

**NCI Criteria**

- 1. Mild; transient memory loss**
- 2. Moderate; short term memory loss; limiting instrumental ADL**
- 3. Severe; long term memory loss; limiting self care ADL**

- 1
- 2
- 3
- ungradable
- no symptom

reset

- Confusion

**NCI Criteria**

- 1. Mild disorientation**
- 2. Moderate disorientation; limiting instrumental ADL**
- 3. Severe disorientation; limiting self care ADL**
- 4. Life-threatening consequences; urgent intervention indicated**
- 5. Death**

- 1
- 2
- 3
- 4
- 5
- ungradable
- no symptom

reset

Fall

**NCI Criteria**

- 1. Minor with no resultant injuries; intervention not indicated**
- 2. Symptomatic; noninvasive intervention indicated**
- 3. Hospitalization indicated**

1    2    3    ungradable    no symptom

reset

Injection site reaction

**NCI Criteria**

- 1. Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)**
- 2. Pain; lipodystrophy; edema; phlebitis**
- 3. Ulceration or necrosis; severe tissue damage; operative intervention indicated**
- 4. Life-threatening consequences; urgent intervention indicated**
- 5. Death**

1    2    3    4    5    ungradable    no symptom

reset

Paradoxical agitation

**NCI Criteria**

- 1. Mild mood alteration**
- 2. Moderate mood alteration**
- 3. Severe agitation; hospitalization not indicated**
- 4. Life-threatening consequences; urgent intervention indicated**
- 5. Death**

1    2    3    4    5    ungradable    no symptom

reset

Sleep apnoea

**NCI Criteria**

- 1. Snoring and nocturnal sleep arousal without apnoeic periods**
- 2. Moderate apnoea and oxygen desaturation; excessive daytime sleepiness; medical evaluation indicated; limiting instrumental ADL**
- 3. Oxygen desaturation; associated with hypertension; medical intervention indicated; limiting self care ADL**
- 4. Cardiovascular or neuropsychiatric symptoms; urgent operative intervention indicated**
- 5. Death**

1  2  3  4  5  ungradable  no symptom

reset

Other 1 (if exists)

**Please specify Other here**

**Grade Other toxicity here**

1  2  3  4  5  Ungradable

reset

Additional other (if exists)

**Please specify additional Other here**

**Grade Additional toxicity here**

1  2  3  4  5  Ungradable

reset

**Which adverse event is the most troublesome?**



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## T1 - 1 hour after Baseline

### T1: Assessed/Not assessed reason

- Assessed today (continue)
- Died
- Not able to be contacted / located
- Too unwell
- Other

reset

### Date of Death (if died)



Now

D-M-Y H:M

### Date-Time of Assessment Today



Now

D-M-Y H:M

### Richmond Agitation-Sedation Scale

- Combative - violent, immediate danger to staff +/- attempting to get out of bed or chair
- Very agitated - Pulls or removes lines, aggressive +/- attempting to get out of bed or chair
- Agitated - Frequent non-purposeful movement, +/- attempting to get out of bed or chair
- Restless - Occasional non-purposeful movement but movements not aggressive or vigorous
- Alert and calm
- Drowsy - Not fully alert, but has sustained awakening to voice (10 seconds or longer)
- Light sedation - Briefly awakens with eye contact to voice (less than 10 seconds)
- Moderate sedation - Any movement or eye opening to voice (but no eye contact)
- Deep sedation - No response to voice, but any movement or eye opening to stimulation by light touch
- Not rousable - No response to voice or stimulation by light touch

reset

### Total dose given in the past hour (including baseline)

### Based on your assessment at this time: was there any benefit?

- Yes
- No
- Don't Know

reset

**Medication Changes**

- Medication of interest dose maintained/continue current dose
- Medication of interest dose decreased
- Medication of interest dose increased (please specify)
- Medication ceased
- New medication added

reset

**Please specify new medication here**

**Please specify new dose here**

**Toxicity Assessment: please select all toxicities and grade accordingly**

Amnesia

- 1    2    3    ungradable    no symptom

reset

Confusion

- 1    2    3    4    5    ungradable    no symptom

reset

Fall

- 1    2    3    ungradable    no symptom

reset

Injection site reaction

- 1    2    3    4    5    ungradable    no symptom

reset

Paradoxical agitation

- 1    2    3    4    5    ungradable    no symptom

reset



Sleep apnoea

1  2  3  4  5  ungradable  no symptom

reset

Other 1 (if exists)

Please specify Other here

Grade Other toxicity here

1  2  3  4  5  Ungradable

reset

Additional other (if exists)

Please specify additional Other here

Grade Additional toxicity here

1  2  3  4  5  Ungradable

reset

Which adverse event is the most troublesome?

### Key questions derived from the Naranjo modified check list

**1. Did the adverse reaction appear after the suspected drug was given?**

- Yes  
 No  
 Don't Know

reset

**2. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?**

- Yes  
 No  
 Don't Know

reset

**3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?**

- Yes  
 No  
 Don't Know

reset

**4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?**

- Yes
- No
- Don't Know

reset

**5. Was the adverse event confirmed by any objective evidence?**

- Yes
- No
- Don't Know

reset



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## T2 - 4 hours after Baseline

### T2: Assessed/Not assessed reason

- Assessed today (continue)
- Died
- Not able to be contacted / located
- Too unwell
- Other

reset

### Date of Death (if died)



Now

D-M-Y H:M

### Date-Time of Assessment Today



Now

D-M-Y H:M

### Richmond Agitation-Sedation Scale

- Combative - violent, immediate danger to staff +/- attempting to get out of bed or chair
- Very agitated - Pulls or removes lines, aggressive +/- attempting to get out of bed or chair
- Agitated - Frequent non-purposeful movement, +/- attempting to get out of bed or chair
- Restless - Occasional non-purposeful movement but movements not aggressive or vigorous
- Alert and calm
- Drowsy - Not fully alert, but has sustained awakening to voice (10 seconds or longer)
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- Moderate sedation - Any movement or eye opening to voice (but no eye contact)
- Deep sedation - No response to voice, but any movement or eye opening to stimulation by light touch
- Not rousable - No response to voice or stimulation by light touch

reset

### Total dose given in the past hour (including baseline)

### Based on your assessment at this time: was there any benefit?

- Yes
- No
- Don't Know

reset

### Medication Changes

- Medication of interest dose maintained/continue current dose
- Medication of interest dose decreased
- Medication of interest dose increased (please specify)
- Medication ceased
- New medication added

reset

### Please specify new medication here

### Please specify new dose here

### Toxicity Assessment: please select all toxicities and grade accordingly

Amnesia

- 1    2    3    ungradable    no symptom

reset

Confusion

- 1    2    3    4    5    ungradable    no symptom

reset

Fall

- 1    2    3    ungradable    no symptom

reset

Injection site reaction

- 1    2    3    4    5    ungradable    no symptom

reset

Paradoxical agitation

- 1    2    3    4    5    ungradable    no symptom

reset

Sleep apnoea

1  2  3  4  5  ungradable  no symptom

reset

Other 1 (if exists)

Please specify Other here

Grade Other toxicity here

1  2  3  4  5  Ungradable

reset

Additional other (if exists)

Please specify additional Other here

Grade Additional toxicity here

1  2  3  4  5  Ungradable

reset

Which adverse event is the most troublesome?

### Key questions derived from the Naranjo modified check list

**1. Did the adverse reaction appear after the suspected drug was given?**

- Yes  
 No  
 Don't Know

reset

**2. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?**

- Yes  
 No  
 Don't Know

reset

**3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?**

- Yes  
 No  
 Don't Know

reset

**4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?**

- Yes
- No
- Don't Know

reset

**5. Was the adverse event confirmed by any objective evidence?**

- Yes
- No
- Don't Know

reset



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## T3 - 24 hours after Baseline

### T3: Assessed/Not assessed reason

- Assessed today (continue)
- Died
- Not able to be contacted / located
- Too unwell
- Other

reset

### Date of Death (if died)



Now

D-M-Y H:M

### Date-Time of Assessment Today



Now

D-M-Y H:M

### Richmond Agitation-Sedation Scale

- Combative - violent, immediate danger to staff +/- attempting to get out of bed or chair
- Very agitated - Pulls or removes lines, aggressive +/- attempting to get out of bed or chair
- Agitated - Frequent non-purposeful movement, +/- attempting to get out of bed or chair
- Restless - Occasional non-purposeful movement but movements not aggressive or vigorous
- Alert and calm
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- Deep sedation - No response to voice, but any movement or eye opening to stimulation by light touch
- Not rousable - No response to voice or stimulation by light touch

reset

### Total dose given in the past hour (including baseline)

### Based on your assessment at this time: was there any benefit?

- Yes
- No
- Don't Know

reset

**Medication Changes**

- Medication of interest dose maintained/continue current dose
- Medication of interest dose decreased
- Medication of interest dose increased (please specify)
- Medication ceased
- New medication added

reset

**Please specify new medication here**

**Please specify new dose here**

**Toxicity Assessment: please select all toxicities and grade accordingly**

Amnesia

- 1    2    3    ungradable    no symptom

reset

Confusion

- 1    2    3    4    5    ungradable    no symptom

reset

Fall

- 1    2    3    ungradable    no symptom

reset

Injection site reaction

- 1    2    3    4    5    ungradable    no symptom

reset

Paradoxical agitation

- 1    2    3    4    5    ungradable    no symptom

reset



Sleep apnoea

1  2  3  4  5  ungradable  no symptom

reset

Other 1 (if exists)

Please specify Other here

Grade Other toxicity here

1  2  3  4  5  Ungradable

reset

Additional other (if exists)

Please specify additional Other here

Grade Additional toxicity here

1  2  3  4  5  Ungradable

reset

Which adverse event is the most troublesome?

### Key questions derived from the Naranjo modified check list

**1. Did the adverse reaction appear after the suspected drug was given?**

- Yes  
 No  
 Don't Know

reset

**2. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was given?**

- Yes  
 No  
 Don't Know

reset

**3. Are there alternative causes (other than the drug) that could on their own have caused the reaction?**

- Yes  
 No  
 Don't Know

reset

**4. Did the patient have a similar reaction to the same or similar drug in any previous exposure?**

- Yes
- No
- Don't Know

reset

**5. Was the adverse event confirmed by any objective evidence?**

- Yes
- No
- Don't Know

reset



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## Medication Cessation (complete this page at any time the medication of interest is ceased)

Date of assessment



Now

D-M-Y H:M

Medication was ceased (related to indication of interest):

- Symptom resolved
- Symptom continued unchanged
- Symptom worsened

reset

Symptom resolved - date of resolution



Today

D-M-Y

Symptom worsened - Grade (NCI)

Medication was ceased (related to other reasons):

- Toxicity
- Patient unable to take medication
- Other

Please specify the other reason medication was ceased

Please specify the patients inability to take medication

What treatment did you subsequently initiate following cessation of the medication of interest?