

# Prevention of delirium (mental confusion) in intensive care using low dose risperidone

<b>Submission date</b> 29/12/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 19/01/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/03/2021	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Delirium is an acute confusional state that often occurs in patients admitted in the Intensive care unit. When patients have this condition they are more likely to develop complications of treatment and have poorer outcomes. This study aims to study whether delirium can be prevented by administering risperidone to patients (an anti-psychotic medication which can be used to reduce agitation in patients with delirium)

### Who can participate?

The study was conducted among adult patients (above 18 years old) admitted to the Intensive care unit.

### What does the study involve?

Written informed consent will be taken from all participants or their legal representatives. Study participants will be randomly assigned to 2 groups. One group will receive risperidone syrup at a dose of 1mg twice daily. The other group will receive a similar-looking placebo treatment. The participants will be screened daily for the presence of delirium using a standard screening tool (CAM-ICU questionnaire)

### What are the possible benefits and risks of participating?

The possible benefits which were considered if the medication was found to be effective included decreased confusion and agitation, a shorter stay in ICU and less sedative medication administration in ICU. Possible side effects included restlessness, drowsiness, allergic reaction to the medication, elevated cholesterol, dryness of the mouth, stiffness of muscles or twitching, changes on an electrocardiogram (recording of the electrical rhythm of the heart). However, these are uncommon when the medicine is given at low doses (such as the dose used in our study) and for short periods.

### Where is the study run from?

The study was conducted in Christian Medical College, Vellore, a tertiary care hospital in South India.

When is the study starting and how long is it expected to run for?  
June 2016 to November 2018

Who is funding the study?  
The study was funded by an Internal research grant provided by the Christian Medical College, Vellore (india)

Who is the main contact?  
Dr Amita Jacob, amita.jacob@cmcvellore.ac.in

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Amita Jacob

**ORCID ID**  
<http://orcid.org/0000-0002-0813-8771>

**Contact details**  
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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
CMC IRB number 10226, CTRI/2018/10/015955

## Study information

**Scientific Title**  
Prevention of delirium in intensive care using low dose risperidone prophylaxis: a randomised placebo controlled trial (PREDELIC trial): a pilot study

**Acronym**

PREDELIC

### **Study objectives**

Low dose risperidone may prevent the onset of delirium in patients in the intensive care unit

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 24/08/2016, Ethics Committee of the Institutional Review Board of Christian Medical College, Vellore (CMC Hospital, Vellore, Tamil Nadu- 632004, India; +91 (0)4162284294; research@cmcvellore.ac.in), ref: 10226(INTERVEN)

### **Study design**

Interventional randomized controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

See additional files

### **Health condition(s) or problem(s) studied**

Delirium in the intensive care unit

### **Interventions**

A computer-generated sequence was generated for randomisation by the project statistician. A pharmacist used this sequence to prepare sequentially numbered identical bottles of Risperidone and an identical placebo syrup. The treating team, the investigators, and the patients were blinded and the allocation was also concealed.

Patients in the intervention arm were given Syrup Risperidone 1mg twice daily per orally beginning immediately after enrolment in the trial. The syrup was continued till the patients either left the intensive care unit or developed delirium. If a patient developed delirium the intervention was stopped and the patient was treated at the discretion of the treating physician. If the patient was intubated and ventilated the syrup was given via a nasogastric tube.

Patients in the control arm were given an identical placebo syrup for the same duration.

### **Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Risperidone

**Primary outcome measure**

1. Incidence of delirium measured using the CAM-ICU scale daily for the length of hospital stay

**Secondary outcome measures**

1. Incidence of complications (such as nosocomial infections and accidental self-extubation) measured from daily review of the progress records and discussion with the clinical team for the length of hospital stay

2. Ventilator free days, defined as the number of days out of 28 on which the patient did not require any form of ventilation (invasive or non-invasive), measured from daily review of the progress records and discussion with the clinical team for the length of hospital stay

3. Duration of ICU stay measured from records of the dates of ICU admission and ICU discharge at the end of hospital stay

4. Duration of hospital stay measured from discharge records at the end of hospital stay

**Overall study start date**

01/06/2016

**Completion date**

30/11/2018

**Eligibility****Key inclusion criteria**

Adults (18>years old) admitted into the medical intensive care unit

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

43

**Total final enrolment**

45

**Key exclusion criteria**

1. No informed consent obtained
2. Neurological disease (including post-cardiopulmonary resuscitation patients)
3. Coma due to drug overdose
4. Alcohol withdrawal syndrome
5. Antipsychotic therapy over the last 30 days
6. Pregnancy/breast feeding
7. Documented delirium prior to ICU admission
8. Difficulty in CAM-ICU assessment (serious auditory or visual disorders, severely mentally disabled; serious receptive aphasia)
9. Predicted ICU-stay less than one day
10. Moribund and not expected to survive two days
11. Known allergy to Risperidone
12. Severe haemodynamic instability (vasopressor dose/inotrope dose > 20 mcg/min)
13. Liver failure (Child-Pugh stage B or C)
14. Renal failure (Stage 3 KDIGO or above)

**Date of first enrolment**

01/02/2017

**Date of final enrolment**

29/11/2018

## **Locations**

**Countries of recruitment**

India

**Study participating centre**

**Christian Medical College**

Medicine 5 Office

Tamil Nadu

Vellore

India

632004

## **Sponsor information**

**Organisation**

Vellore Christian Medical College Foundation

**Sponsor details**

Christian Medical College

Vellore

India

632002  
+91 (0)4162284294  
research@cmcvellore.ac.in

**Sponsor type**

University/education

**Website**

<https://www.vellorecmc.org/>

**ROR**

<https://ror.org/020y1sx51>

## **Funder(s)**

**Funder type**

University/education

**Funder Name**

Christian Medical College, Vellore

**Alternative Name(s)**

CMC Vellore, CMC

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

India

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a peer reviewed journal.

**Intention to publish date**

31/12/2021

**Individual participant data (IPD) sharing plan**

The anonymous raw data will be available on request. It will be available for meta-analysis for the next 10 years. Requests can be sent to Amita Jacob (amita.jacob@gmail.com). Specific consent for the same has not been obtained.

## IPD sharing plan summary

Available on request

### Study outputs

Output type

[Participant information sheet](#)

[Protocol file](#)

Details	Date created	Date added	Peer reviewed?	Patient-facing?
		04/02/2021	No	Yes
		04/02/2021	No	No