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

Submission date
29/12/2020

Recruitment status
No longer recruiting

Registration date
19/01/2021

Overall study status
Completed

Last Edited
15/03/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Delirium in 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

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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 nasagastric 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 ssessment (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>20mcg/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
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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	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			04/02/2021	No	Yes
Protocol file			04/02/2021	No	No