Christian Medical College, Vellore
Department of Medicine

PREvention of DELirium in Intensive Care using low dose risperidone prophylaxis: a randomised placebo controlled trial (PREDELIC trial)

INFORMARION SHEET

You are being requested to participate/allow your relative to participate in a study to see if a drug (risperidone) will prevent the development of delirium, which is a common condition seen in patients admitted to Intensive Care Units. We hope to include 100 people in the study.

What is delirium?

Delirium, is a clinical condition where the person has difficulty in attention and concentration and which results in mental confusion. Such confusion and agitation means that the person is not aware of his surroundings and will not be cooperative for treatment. Delirium is a common problem that affects patients admitted to the intensive care units (ICU).

Patients who develop delirium have greater cognitive problems after discharge from hospital, usually have a longer period of hospitalization resulting in higher cost of care and are also at an increase risk of death. Delirium is worsened by infections, certain medications and is more common among older people.

The treatment of delirium includes the management of the underlying medical condition and the use of certain medications like risperidone. While such medication helps people in whom delirium occurs, there is limited scientific evidence to use such strategies to prevent the condition. There have been a few studies done in a small number of people, where medications like risperidone are shown to be useful in preventing delirium. However, there is no definitive evidence to support the routine use of such medication to prevent delirium in ICU.

What is risperidone?

Risperidone is a newer medication, which is now routinely employed in clinical practice. It is routinely used to treat confusion and agitation in people and is used to treat certain forms mental illness. It is routinely use to treat established delirium in hospitalised patients. It is licenced for use in India.

What is the aim of this study?

This study aims to investigate the effectiveness of the medicine risperidone in preventing delirium from occurring to patients admitted in the ICU. Half the patients who join the study will be given a small dose of risperidone, while the rest will receive a placebo.

What will happen if my relative joins the study?

All patients who join this study will be provided standard treatment and care in the ICU. However, half of the patients in the study will receive a low dose of 1mg risperidone

twice daily and the other half will receive placebo (dummy) tablets. Neither you nor the treating doctors will know which patients are receiving the active treatment or placebo (dummy) tablets. All the patients will be checked daily to see if they have delirium and will be monitored for side-effects. The medicine along with monitoring will be continued for a total of 28 days.In case any patient develops delirium despite treatment the study medication will be stopped and the delirium will be treated using standard treatment protocol.

What are the possible side effects of risperidone?

Risperidone is a relatively safe medicine with few side effects at low dose. However, these may include dry mouth, dizziness, headache and somnolence.All patients will be routinely monitored to check their vital signs.

What will happen is you develop any study related injury?

We do not expect any injury to happen but if you do develop any side effects or problems due to the study medication, these will be treated free of cost to you. However, we are unable to provide monetory compensation to you.

Will you have to pay for the study tablets?

Both risperidone and the placebo (dummy tablet) will be given free for the period of hospitalization in ICU.

Will your personal details be kept confidential?

Yes. Your personal details will be kept confidential. If the results of the study are published in a medical journal, you will not be identified by name in any publication or presentation of the study results. However, your medical notes may be reviewed by people associated with the study.

Can I withdraw from this study after it starts?

Your relatives participation in this study is entirely voluntary. You can withdraw consent for the study at any time and this will not affect your relative's care and treatment.

If you have any further questions, please contact:

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Department of Medicine

CONSENT TO TAKE PART IN A CLINICAL TRIAL

Study Title: PREvention of **DEL**irium in **I**ntensive **C**are using low dose risperidone prophylaxis: a randomised placebo controlled trial (PREDELIC trial)

Study Number

Patient Name
Hospital Number
Age

(Subject)
(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation/my relative's participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity/my relative's identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). [ ]

(v) I agree to/let my relative take part in the above study. [ ]

(vi) I am aware of the Audio-visual recording of the Informed Consent. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable

Date: _____/_____/_____

Signatory's Name:
_____ Signature:

Or

Signature (or Thumb impression) of the Representative: _____

Relationship to patient_____

Date: _____/_____/_____

Signatory's Name: _____

Signature of the Investigator: _____

Date: _____/_____/_____

Study Investigator's Name: _____

Signature or thumb impression of the Witness: _____

Date: _____/_____/_____

Name & Address of the Witness: _____