

A randomised controlled trial of intra-muscular Lorazepam versus intra-muscular Haloperidol and Promethazine in the management of psychotic agitations and aggression

Submission date 29/04/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/04/2002	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 02/10/2007	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Prathap Tharyan

Contact details

Department of Psychiatry Unit II
Mental Health Center
Christian Medical College
Bagayam Vellore
India
632 002
+91 (416) 262603 ext 4259
dralexander_in@yahoo.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym

TREC-INDIA (Tranquilizacao Rapida-Ensaio Clinico; translated from Portuguese - 'Rapid Tranquillisation-Clinical Trial')

Study objectives

To compare interventions commonly used for controlling agitation or violence in people with serious psychiatric disorders.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Serious mental illnesses combined with overt aggression or agitation

Interventions

1. Haloperidol (up to 10 mg IM) with promethazine (up to 50 mg IM)
2. Lorazepam (4 mg IM)

Doses are not fixed and are at the discretion of the attending doctors.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Lorazepam, Haloperidol, Promethazine

Primary outcome measure

1. Tranquil or asleep by 4 hours
2. The time of onset of tranquillisation and/or sleep

Participants were considered to be tranquil when they were calm and not exhibiting agitated, aggressive or dangerous behaviour. Patients were considered to be asleep if, on inspection, they appeared to be sound asleep and were not aroused by ambient disturbances.

Secondary outcome measures

These assessments were conducted only on participants who were awake, as extrapyramidal symptoms are usually not apparent during sleep or, in the case of dystonia or akathisia, are likely to prevent sleep:

1. Clinical Global Impression Severity (CGIS) scale at entry
2. CGIImprovement (CGII) scale with respect to aggression and violence
3. SimpsonAngus extrapyramidal side-effects rating scale
4. Barnes Akathisia Scale
5. Any other clinically important adverse effects, especially dystonia

Other outcomes within the first 4 hours were:

6. The use of additional medication for control of agitated or aggressive behaviour
7. The use of physical restraints
8. The need for further medical attention and numbers absconding

Participants were also followed up 2 weeks later to check for adverse effects or adverse outcomes and compliance with oral medication.

Overall study start date

01/01/2002

Completion date

31/12/2002

Eligibility**Key inclusion criteria**

Patients need acute intramuscular sedation because of disturbed and dangerous behaviour as decided by the attending physician.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

200

Key exclusion criteria

1. The clinician believes that one of the two treatments represents an additional risk for the patient
2. Feels that one of the two treatments is definitely indicated for a given patient

Date of first enrolment

01/01/2002

Date of final enrolment

31/12/2002

Locations**Countries of recruitment**

India

Study participating centre

Department of Psychiatry Unit II

Bagayam Vellore

India

632 002

Sponsor information**Organisation**

Christian Medical College and Hospital (India)

Sponsor details

Bagayam

Vellore

India

632002

Sponsor type

Hospital/treatment centre

Website

<http://www.cmch-vellore.edu/>

ROR

<https://ror.org/00c7kvd80>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Christian Medical College and Hospital (India) - Fluid Research Grant

Funder Name

The Cochrane Schizophrenia Group (CSG) (UK) - supported with funding for sundries

Funder Name

The doctors and nurses of Vellore freely gave support, enthusiasm and skill.

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/07/2004		Yes	No