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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

Registration date
29/04/2002

Overall study status
Completed

Last Edited
02/10/2007

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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)

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

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