ISRCTN83261243 https://doi.org/10.1186/ISRCTN83261243

TREC2 - Rapid tranquillisation for agitated patients in emergency psychiatric rooms in Rio de Janeiro. A randomised trial of intramuscular Haloperidol versus intramuscular Haloperidol + Promethazine.

Submission date 31/08/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [X] Results [ ] Individual participant data
Registration date 13/09/2005	**Overall study status** Completed	
Last Edited 01/11/2007	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.fotolog.net/trec

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
TREC - Rapid Tranquillisation Clinical Trial (Tranquilização Rápida-Ensaio Clínico)

Study objectives
The trial was undertaken to test the risks and benefits of adding promethazine to haloperidol for rapid intramuscular tranquillisation.

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 violence

Interventions

1. Haloperidol (up to 10 mg intramuscular [IM])
2. Haloperidol (up to 10 mg IM) with promethazine (up to 50 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)
Promethazine, haloperidol

Primary outcome measure
Tranquil or asleep by 20 minutes after medication is given

Secondary outcome measures
1. Asleep by 20 minutes
2. Tranquil or asleep by 40, 60 and 120 minutes
3. Physically restrained or given additional medication within 2 hours
4. Severe adverse events during the subsequent 24 hours
5. Another episode of agitation/aggression during the subsequent 24 hours
6. Needing additional visits from the doctor during the subsequent 24 hours
7. Overall antipsychotic load in the first 24 hours
8. Still in hospital after 2 weeks

Overall study start date
06/01/2004

Completion date
01/07/2004

Eligibility

Key inclusion criteria
People are eligible for trial entry if:
1. It is clear that they need acute intramuscular sedation because of disturbed and dangerous behaviour thought to be due to serious mental illness
2. The clinician is uncertain about the benefits and risks of the comparator medications

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
600

Key exclusion criteria
People are not eligible for trial entry if the clinician believes that one treatment represents an additional risk for the patient

Date of first enrolment
06/01/2004

Date of final enrolment
01/07/2004

Locations

Countries of recruitment
Brazil

Study participating centre
INCQS-FIOCRUZ
Rio de Janeiro
Brazil
21045-900

Sponsor information

Organisation
National School of Public Health (ENSP), Oswaldo Cruz Foundation (FIOCRUZ) (Brazil)

Sponsor details
Rua Leopoldo Bulhões 4036/816 Manguinhos
Rio de Janeiro
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21041-210

Sponsor type
Charity

Website
http://www.ensp.fiocruz.br

ROR
https://ror.org/04jhswv08

Funder(s)

Funder type
Research council

Funder Name
The National Council for Research and Development (Consejo Nacional de Desarrollo Cientifico y Tecnologico [CNPq]) (Brazil)

Funder Name
Regional Health Authorities (Brazil) - donated drugs

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	27/10/2007		Yes	No