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Rapid safe tranquillisation for acutely disturbed people attending public psychiatric emergency clinics in Rio de Janeiro

Submission date
08/03/2002

Recruitment status
No longer recruiting

Registration date
08/03/2002

Overall study status
Completed

Last Edited
21/05/2019

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Rapid safe tranquillisation for acutely disturbed people attending public psychiatric emergency clinics in Rio de Janeiro

Acronym
TREC-Rio = Rapid Tranquillisation Clinical Trial (Tranquilizacao Rapida-Ensaio Clinico)

Study objectives
TREC-Rio will compare midazolam with haloperidol-promethazine mix for treatment of agitated patients in emergency psychiatric rooms of Rio de Janeiro, Brazil.

Ethics approval required
Old ethics approval format

Ethics approval(s)
TREC-Rio has been approved by the ethics committees of institutions in charge of research and local ethics committees of each hospital involved.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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]) with promethazine (up to 50 mg IM)
2. Midazolam (up to 15 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)
Midazolam, haloperidol-promethazine

Primary outcome measure
Tranquillisation at 20 minutes.

Secondary outcome measures
Effects on other measures of morbidity, recorded at 24 hours and two weeks.

Overall study start date
01/01/2003

Completion date
01/01/2004

Eligibility

Key inclusion criteria
1. It is clear that they need acute intramuscular sedation because of disturbed and dangerous behaviour thought to be due to serious mental illness; and
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
300

Total final enrolment
301

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
01/01/2003

Date of final enrolment

01/01/2004

Locations

Countries of recruitment
Brazil

Study participating centre
Oswaldo Cruz Foundation
Rio de Janeiro
Brazil
RJ 21041-210

Sponsor information

Organisation
Oswaldo Cruz Foundation (Brazil)

Sponsor details
National School of Public Health
Manguinhos
Av. Leopoldo Bulhões 1480/sala 816
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Sponsor type
Research organisation

Website
http://www.fiocruz.br

ROR
https://ror.org/04jhswv08

Funder(s)

Funder type
Government

Funder Name
There are no specific extramural funds.

Funder Name
The British Council (UK) - facilitated international contact

Funder Name
CAPES Foundation (Coordenacao de Aperfeicoamento de Pessoal de Nivel Superior) (Brazil) - facilitated international contact

Funder Name
The Ministry of Health (Brazil) - seconded the principal investigator for 2 years

Funder Name
Regional Health Authorities (Brazil) - donated drugs

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

Funder Name
The doctors and nurses of Rio 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?
Protocol article	protocol	16/10/2002		Yes	No

Results article	results	27/09/2003	21/05/2019	Yes	No