

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 08/03/2002	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 21/05/2019	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

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Contact details

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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

Rio de Janeiro

Brazil

RJ 21041-210

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