

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

<b>Submission date</b> 08/03/2002	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 08/03/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/05/2019	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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**

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

**Study type(s)**

Quality of life

**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(s)**

Tranquillisation at 20 minutes.

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Not Specified

**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)

## 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

### 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?
<a href="#">Results article</a>	results	27/09/2003	21/05/2019	Yes	No
<a href="#">Protocol article</a>	protocol	16/10/2002		Yes	No