

TREC-SAVE: a trial for aggressive or violent seriously mentally ill people

Submission date 14/12/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 04/03/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 28/07/2011	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

Randomised controlled trial comparing mechanical restraints with seclusion for aggressive mentally ill people in emergency psychiatric hospitals

Acronym

TREC-SAVE

Study objectives

The trial aims to test the hypothesis that one procedure (seclusion or restraints) is more effective and/or more safe for the management of agitated and violent people in emergency psychiatric hospitals.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee from Philippe Pinel Institute in Rio de Janeiro approved on the 24th February 2010 (ref: 56/2010)

Study design

Single-centre randomised open controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Aggressive/violent mental illness

Interventions

1. Use of four point physical restraint (cotton bands) and policy of close recording of mental state, behaviour, wellbeing, in addition to standard use of medication.
2. Use of secure seclusion room and policy of close recording of mental state, behaviour, wellbeing, in addition to standard use of medication.

In the case of Instituto Philippe Pinel secure seclusion involves a locked room with minimal bedding but airy and with good day light though barred windows with no frame or glass open to the nursing station or passing patients.

The total duration of each intervention is exactly the primary outcome, but follow-up in each arm will last by two weeks.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Time to release from restraints or seclusion

Secondary outcome measures

1. Safe resolution of episode, measured 24 hours after the beginning of the episode
2. Time in restriction, measured 24 hours after the beginning of the episode
3. Further episode, measured 24 hours after the beginning of the episode
4. Need to call the doctor on an emergency basis, measured 24 hours after the beginning of the episode
5. Refusal of oral medication, measured 24 hours after the beginning of the episode
6. Amount of medication and how administered, measured 24 hours after the beginning of the episode
7. Acceptability to patient/staff, measured 24 hours after the beginning of the episode
8. Adverse effects, measured at 2 weeks
9. Time to discharge, measured at 2 weeks

Overall study start date

16/06/2010

Completion date

30/04/2011

Eligibility**Key inclusion criteria**

1. Anyone (no age or gender limits) thought to have a serious mental illness admitted to the hospital who has a degree or risk of aggression or violent behaviour that endangers themselves or others
2. Who is thought by medical and nursing staff to need some form of physical restriction
3. For whom the medical and nursing staff have doubt as to whether one form of restriction is better than the other

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

100 people

Key exclusion criteria

1. Anyone for whom either or both packages of care are contraindicated by either medical or nursing staff
2. Anyone already randomised in this trial

Date of first enrolment

16/06/2010

Date of final enrolment

30/04/2011

Locations**Countries of recruitment**

Brazil

Study participating centre

Av Brasil 4365 Manguinhos

Rio de Janeiro

Brazil

21040-900

Sponsor information**Organisation**

National Institute of Quality Control in Health (Brazil)

Sponsor details

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Sponsor type

Government

Website

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ROR

Funder(s)

Funder type

Research organisation

Funder Name

National Institute of Quality Control in Health - Oswaldo Cruz Foundation (Brazil)

Funder Name

Federal University of Rio de Janeiro (UFRJ) (Brazil) - School of medicine

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	20/07/2011		Yes	No