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

Submission date	Recruitment status	[ ] Prospectively registered
14/12/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/03/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/07/2011	Mental and Behavioural Disorders	[ ] Record updated in last year

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

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
http://www.incqs.fiocruz.br

ROR

https://ror.org/04jhswv08

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