ISRCTN70589121 https://doi.org/10.1186/ISRCTN70589121

Randomised controlled trial on seclusion and mechanical restraint

Submission date	Recruitment status
06/06/2006	No longer recruiting
Registration date	**Overall study status**
25/08/2006	Completed
Last Edited	**Condition category**
10/05/2010	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] 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

Contact name
Prof Tilman Steinert

Contact details
ZfP Weissenau
Weingartshoferstr. 2
Ravensburg
Germany
88214
+49 (0) 751/7601-2738
tilman.steinert@zfp-weissenau.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
Isofix

Study objectives
There is a difference in the subjective assessment of patients regarding the restriction of human rights after seclusion or mechanical restraint was being conducted.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethical Committee of University of Ulm on the 11th November 2002 (amendment approved 20th October 2005) (ref: 136/2002).

Study design
Cohort design with optional randomisation

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Aggressive behaviour or self-directed aggression

Interventions
Seclusion and mechanical restraint

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Subjective assessment of patients' restrictions of a human rights score composed of human dignity, autonomy, freedom of movement, interpersonal contact and perceived coercion during conducting the measure.

Secondary outcome measures
Duration of measure, complications and safety.

Overall study start date
05/03/2004

Completion date
05/03/2006

Eligibility

Key inclusion criteria
1. Patients for whom coercive measures are indicated
2. Diagnosis F2, F3 or F6 in International Classification of Diseases (ICD-10)
3. Informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
220

Key exclusion criteria
1. Severe intellectual deficits
2. Continously severely disturbed mental state
3. Poor German
4. Inclusion into study during a former admission
5. Missing informed consent
6. Exclusion Criteria to randomisation:
a. definite wish of the patient not to receive one but the other measure
b. contraindication to one measure by the psychiatrist

Date of first enrolment
05/03/2004

Date of final enrolment
05/03/2006

Locations

Countries of recruitment
Germany

Study participating centre
ZfP Weissenau
Ravensburg
Germany
88214

Sponsor information

Organisation
University of Ulm (Germany)

Sponsor details
Department of Psychiatric Health Care Research
Psychiatric Department I
ZfP Weissenau
Weingartshoferstr. 2
Ravensburg
Germany
88214
+49 (0) 751/7601-0
tilman.steinert@zfp-weissenau.de

Sponsor type
University/education

Website
http://www.zfp-web.de/K2/index.php3

ROR
https://ror.org/032000t02

Funder(s)

Funder type
University/education

Funder Name
University of Ulm (Germany) - Department of Psychiatric Health Care Research

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?
Results article	results	14/01/2010		Yes	No