

Randomised controlled trial on seclusion and mechanical restraint

Submission date

06/06/2006

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

25/08/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

10/05/2010

Condition category

Mental and Behavioural Disorders

☐ 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. Continuously 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