

Effectiveness, neuropsychological distress, teamwork, and ergonomics with procedures conducted in the i-Suite surgical environment

Submission date 31/03/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/04/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/04/2008	Condition category Surgery	<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
Prof Axel Ekkernkamp

Contact details
Department of Orthopaedic and Trauma Surgery
Unfallkrankenhaus Berlin
Warener Str. 7
Berlin
Germany
12683
axel.ekkerkamp@ukb.de

Additional identifiers

Protocol serial number
ukb_6.1_2008

Study information

Scientific Title

Acronym

ENTERPRISE

Study objectives

A novel, integrated operating theatre environment (i-Suite™, Stryker) reduces the average or time in trauma, orthopaedic, and visceral procedures (i.e., the time interval from the patient's entry to discharge from the theatre) compared to a modern, conventional operating room by 20 ± SD 50 minutes (equating a moderate Cohen's effect size of 0.4 = 20/50).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board of the Charité University Medical Center. Date of approval: 06/02 /2008 (ref: EA1/004/08)

Study design

Single-centre, randomised controlled trial.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

All elective orthopedic and/or trauma, or visceral surgical procedures.

Interventions

Experimental intervention:

General orthopedic (e.g., total joint replacement), trauma, and surgical procedures (e.g., fracture fixation, abdominal and thoracic surgery) conducted in one of two integrated i-Suite operating theatres.

Control intervention:

A similar range of procedures, conducted in a conventional, last-generation operating theatre.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

Time interval from the patient's entry to discharge from the operating theatre.

Key secondary outcome(s))

1. Team-centered endpoints, recorded during operation:

1.1. Stress of surgeons, anaesthetists, and scrub nurses in charge, as measured by short

questionnaire assessments and biological markers in saliva (cortisol and beta-endorphine) immediately before and after surgery

1.2. Quantity and quality of distracting events (e.g., phone calls, door openings, technical failures) that may prolong or compromise the procedure

1.3. Comfort and climate (e.g., space, noise, and others)

1.4. Perceived success of the procedure

1.5. Team interaction

2. Patient-centered endpoints:

2.1. Critical incidents, intra- and post-operative complications, monitored during hospital stay until discharge

2.2. Quality of Life (EuroQol [EQ5D]) questionnaire at baseline, discharge and 6 months after surgery (by post)

Completion date

01/05/2009

Eligibility

Key inclusion criteria

1. Consecutive patients ≥ 18 years of age scheduled for orthopedic and/or trauma, or visceral surgery on weekdays between 8.00 am and 4.00 pm (core working hours)

2. Full ability to provide written informed consent

3. Both men and women

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

Key exclusion criteria

1. Acute, emergency, or life-saving surgery

2. Refusal of trial participation

Date of first enrolment

01/05/2008

Date of final enrolment

01/05/2009

Locations

Countries of recruitment

Germany

Study participating centre

Department of Orthopaedic and Trauma Surgery

Berlin

Germany

12683

Sponsor information

Organisation

Unfallkrankenhaus Berlin Trauma Center (Germany)

ROR

<https://ror.org/011zjcv36>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Unfallkrankenhaus Berlin Trauma Center (main funding body) (Germany)

Funder Name

Additional funding will be sought from Stryker (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration