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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 11/04/2008	**Overall study status** Completed	
Last Edited 11/04/2008	**Condition category** Surgery	

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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)

Overall study start date
01/05/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
"Intent to treat" (ITT) population: 2 x 200 patients

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
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Sponsor information

Organisation
Unfallkrankenhaus Berlin Trauma Center (Germany)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.ukb.de

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

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