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Computer-assisted ALerting and Monitoring System

Submission date	Recruitment status	[_] Prospectively registered
13/05/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/06/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/07/2012	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
N/A

Study information

Scientific Title

Acronym
CALMS

Study objectives
To determine if advanced signal processing and data fusion techniques (contained in a novel computer module called the 'BioSign Monitor') when applied to physiological signals obtained from a standard patient monitor can detect clinically significant changes in the condition of patients differently to current standard care. Specifically patients will be monitored in the immediate post-operative period or following emergency admission to hospital for non-surgical conditions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Non-invasive monitoring of patients undergoing high-risk surgery, or admitted for an acute medical problem.

Interventions
Comparison of effect of mandated 4/5 channel physiological monitoring on clinically significant event rates in high-risk patients compared to patients in the same group receiving usual care and monitoring. Nested within the monitoring arm is a within-patient assessment of the senstivity and specificity of 'BioSign', a novel computer data fusion device which analyses physiological tracees in real time, to determine if it can detect the clinically significant events earlier than current monitoring and usual standards of care.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
The primary goal of the study is to determine the specificity and sensitivity of a package of signal processing and data fusion techniques (the 'BioSign Monitor') to detect clinically significant deteriorations in the condition of patients in the 72 hours following major surgery or emergency admission. The 'gold standard' against which the BioSign Monitor will be compared is the rate of clinically significant events detected using standard care alone by the ward care team.

Secondary outcome measures
1. To determine if the BioSign Monitor detects clinically significant deteriorations in the condition of patients before the patients care team notes them
2. To determine if the BioSign Monitor, using pattern recognition techniques integrated over five physiological variables, can predict clinically significant changes in a single physiological variable before they are detected by single channel limit alarms
3. To determine if mandated continuous standard 5 channel physiological monitoring alters the rate of detection of clinically significant events
4. To determine if mandated continuous 5 channel physiological monitoring alters the hospital mortality or hospital length of stay in patients following major surgery or following emergency admission
5. To determine the optimal threshold for event detection in the BioSign Monitor to maximize true positive detections and minimize false positive and false negative detections
6. To provide a high quality, well annotated database of physiological data on post-operative and urgent medical patients to allow further development of data fusion algorithms.

Overall study start date
01/10/2003

Completion date
30/06/2005

Eligibility

Key inclusion criteria
Male or female patients, 18 years or older, undergoing 'high-risk' elective or emergency surgical procedures, or presenting with an acute medical problem of at least moderate severity.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
400

Key exclusion criteria
Those subject to additional protections; this includes pregnant women and persons with mental illness or disability, patients refusing consent, children (less than 18 years old), patients undergoing cardiac surgery, patients undergoing surgery for burns, patients undergoing surgery of the thoracic aorta, patients whose anatomy precludes the use of the required monitoring, patients expected to be sufficiently mobile to leave the bed space unaided within 72 hours of operation or recruitement.
Patients in the intensive care unit.

Date of first enrolment
01/10/2003

Date of final enrolment
30/06/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Adult Intensive Care Unit
Oxford
United Kingdom
OX39DU

Sponsor information

Organisation
Oxford BioSignals Ltd (UK)

Sponsor details
Magdalen Centre
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Sponsor type
Industry

ROR
https://ror.org/02q0ygf45

Funder(s)

Funder type
Industry

Funder Name
Oxford BioSignals Ltd (UK)

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	01/07/2006		Yes	No