

Computer-assisted ALerting and Monitoring System

Submission date 13/05/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 10/06/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 30/07/2012	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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

Study type(s)

Not Specified

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 sensitivity and specificity of 'BioSign', a novel computer data fusion device which analyses physiological traces 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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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 recruitment.

Patients in the intensive care unit.

Date of first enrolment

01/10/2003

Date of final enrolment

30/06/2005

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Adult Intensive Care Unit

Oxford

United Kingdom

OX39DU

Sponsor information

Organisation

Oxford BioSignals Ltd (UK)

ROR

<https://ror.org/02q0ygf45>

Funder(s)

Funder type

Industry

Funder Name

Oxford BioSignals Ltd (UK)

Results and Publications

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