The analysis of Medical Emergency Teams in the Netherlands, a multi center approach. The COMET study.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23531

Source
Nationaal Trial Register

Brief title
COMET, Cost and Outcomes analysis of Medical Emergency Teams

Health condition

Deteriorating patient
Medical Emergency Team
Rapid Response System
Rapid Response Team
Modified Early Warning Score
MEWS
Situation-Background-Assessment-Recommendation
SBAR

Sponsors and support

Primary sponsor: Funding is provided by the participating centers and primarily from the Academic Medical Center in Amsterdam
Source(s) of monetary or material Support: Funding is provided by the participating centers and primarily from the Academic Medical Center in Amsterdam

Intervention

Outcome measures

Primary outcome

1. Cardiac arrest rate;

2. Unplanned ICU admission rate (following the NICE registry);

3. Unexpected death rate.

These endpoints will be analyzed as a composite endpoint and as separate outcomes.

Rate is defined as number of outcomes per 1000 admitted patients.

Secondary outcome

1. Total mortality (irrespective of code);

2. Hospital Length of Stay (LOS);

3. ICU length of stay;

4. Number of RRT calls per 1000 admitted;

5. Costs from a hospital perspective.

Study description

Background summary

In this multicenter trial, the effectiveness of an RRS is analyzed using a before after design incorporating a generalized estimating equations analysis to analyze for trends and study the associated costs of implementating an RRS. Through phased introduction of the RRS components, it can be hypothesized as to were the possible effectiveness may reside ie early detection or assistance of a specialized ICU team. Effectiveness will be analyzed by the composite and separate outcomes including cardiac arrest rate, unplanned ICU admission rate and unexpected death rate.

Study objective

Early recognition of deteriorating patients is key to possible effectiveness of an RRS. Therefore, phased introduction of the afferent limb (aimed at detection) followed up by the implementation of the efferent limb (the Medical Emergency Team) will enable to analysis the additive effect of an RRT compared to earlier detection at the bedside.

Study design

The comet study is set-up as a before after trial (5 months before and 5 months after comparison) with the direct ability to perform a generalized estimating equations analysis to analyze for trends.

This successive implementation of the components that build up an RRS, enables differentiated analysis of the additive effect of an RRT compared to the effectiveness of sole implementation of the MEWS/SBAR instruments. Also this study incorporates ample time for sufficient implementation compared to previous studies which analyzed complex interventions.

Intervention

Following a baseline measurements phase of five months, the MEWS and SBAR instruments are implemented and primary endpoints are measured for seven months. Measurements of vital parameters is protocolized using the Modified Early Warning Score (MEWS) which is based on a sum score for the vital parameters. On the basis of the degree of derangement from normality, points are scored for each included parameter and at a threshold set at three for the sum score, action towards the physician is compulsory. Measurement of the MEWS is left ‘on clinical grounds’ and is thus measured whenever one or more points are scored at either regular rounds or whenever a nurse ‘feels worried’ about the clinical condition of the patient.

After which a score of three is found, communication of the information with the physician is structured using the Situation-Background-Assessment-Recommendation (SBAR) tool.

Following these seven months, a Rapid Response Team (RRT) is implemented which can be called to the patient bedside by either the physician or nurse according to an activation protocol. The RRT consists out of an ICU clinician (intensivist/fellow at least ACLS certified) and an ICU nurse. The team is available 24/7 and responds within 10 minutes to the patient. Following initial contact by the nurse, the (attending) physician has 30 minutes to evaluate and initiate a treatment plan for the patient. In the following 60 minutes, the patient’s clinical condition should improve or otherwise the RRT has to be notified. If the physician is not able to keep to these timeframes and protocol, mandatory activation of the RRT by the nurse is clearly stated. This phase takes 17 months which includes the after measurement phase which is five months.

Contacts

Public
PO Box 22660
Jeroen Ludikhuize
Academic Medical Center Amsterdam
Department of Quality Assurance and Process Innovation
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5665991
Scientific
PO Box 22660
Jeroen Ludikhuize
Academic Medical Center Amsterdam
Department of Quality Assurance and Process Innovation
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5665991

Eligibility criteria

Inclusion criteria

All adult patients admitted to the study wards and all primary outcomes are included if transpired on nursing wards.

Exclusion criteria

Outcomes on higher care wards like Medium Care, Intensive Care etc. are excluded from analysis.

Study design

Design

Study type:	Interventional
Intervention model:	Factorial

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2009
Enrollment:	27720
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-01-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2581
NTR-old	NTR2706
Other	METC : W11_008
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A