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Med-on-@ix: Telemedical support for prehospital Emergency Medicals Services in a prospective controlled trial

Submission date	Recruitment status	[_] Prospectively registered
15/02/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/09/2017	Other	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.medonaix.de

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Project-No.: 01MB07022

Study information

Scientific Title
T-EMS2-Trial: TEleMedical Support in Emergency Medical Services in a prospective controlled trial

Acronym
T-EMS2-Trial

Study objectives
The hypothesis is that the use of telemedical assistance (TMA) in a physician-powered Emergency Medical Service (EMS) will lead to
1. Improved guidelines coherence for stroke and acute coronary syndrome
2. Improved treatment time intervals for stroke and ST-Elevation myocardial infarction
3. Improved patient safety and patient outcome
4. Improved choice of appropriate hospital respiratory facility
5. Improved quality of pre-hospital diagnosis
and that the implementation of electronic documentation with integrated plausibility check will lead to
6. Improved quality of documentation in respect of medical and research purposes.
Secondary, the usability and feasibility of the system as well as the percentage of safe transferability of monitoring data will be observed and used for further improvement of the system.
Added 17/05/2011: We did not use electronic documentation as standard procedure. To ensure comparable data sources we used paper based documentation in both groups. Additionally we tested electronic documentation in some cases.

As of 19/05/2011 the study design has been updated. The previous study design was a 'Single centre prospective interventional randomised controlled trial'.
The patients were not randomised to ensure case numbers were high enough for the trial's purposes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local ethics committee approved on the 24/032010 (ref: EK 141/09)

Study design
Prospective, controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Because of the fact, that patients receive at least standard EMS-care, no specific patient information material was developed. The community has been informed about the research project with local newspaper articles and with local TV. Patients may receive additional information via the project website: www.medonaix.de

Health condition(s) or problem(s) studied
Acute stroke; acute coronary syndrome; all other medical emergencies requiring Emergency Medical Service

Interventions
The study will be held in the EMS of Aachen. Within a period of five months totally, all inhabitants who have to make use of the EMS by calling the nationwide emergency phone number 112, will receive at least the recent standard in German EMS. This includes an EMS-physician staffed ambulance disposed according to predefined criteria given by the dispatch centre. There will be no special selection of patients at this stage of the study. The dispatcher decides which ambulance receives the mission on the basis of location and availableness. In this way patients receive either standard emergency care with or without additional telemedical assistance. Neither patients nor EMS-physicians or paramedics have influence over the dispatching.

Intervention group:
Use and documentation of Telemedical Assistance (TMA):
All monitoring data (ECG, blood pressure, pulseoximetry etc) is automatically transferred to a specialised computer workstation, where a TMA-physician observes the EMS-mission and advises the EMS-Team. Beside the monitoring data it is possible to transmit pictures (digital camera), 12-lead-ECG and video-stream (camera in ambulance) as and when required. The EMS-Team and the TMA-physician are able to communicate via a special, integrated mobile phones with headsets. All TMA-physicians are experienced, certified EMS-physicians. In the TMA-workstation they have access to several checklists, guidelines and medical online databases to provide additional information as needed.
All data transmission is carried out with a specifically developed transmission unit, using mobile phone networks. Up to date ciphering technologies are integrated to guaranty a maximum of data safety. (P3 communications, Aachen, Germany)
Agreement of the patient to transfer these data will be obtained in every case of a conscious patient.
Every EMS-Mission will be documented using an electronic documentation software with integrated plausibility check. For this purpose a specifically software was developed during the research project.
Hardware: Motion C5 Tablet PC, Motion Computing, Germany. Data of the EMS-documentation is used to evaluate coherence with medical guidelines.
All procedures are in accordance with national laws and guidelines as well as laws and guidelines of the European Union.

In the admitting hospital standard patient care is provided. Relevant time intervals are measured with the hospital IT infrastructure (e.g. time of Computer Assisted Tomography [CAT] scan, time of Percutaneous Coronary Intervention [PCI]).

Control group:
Documentation in standard care:
All missions are documented on standardised paper based protocols fulfilling current recommended national standard of the German Interdisciplinary Association of Critical Care Medicine (DIVI 4.2). Standard patient care is provided in EMS. Data of the EMS-documentation is used to evaluate coherence with medical guidelines
In the admitting hospital standard patient care is provided. Relevant time intervals are measured with the hospital IT infrastructure (e.g. time of CAT scan, time of PCI).

Follow-up ends, when the last of these patients is discharged from hospital. There is no further follow-up planned after the hospital discharge.

Added 17/05/2011: Electronic documentation was used as an additional tool in some missions. Standard procedure in both groups was paper based documentation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Guideline coherence for stroke and acute coronary syndrome: measured with data of the medical records / EMS-documentation
2. Improved treatment time intervals for stroke and ST-Elevation myocardial infarction
2.1. on scene time (all patients)
2.2. call to hospital arrival time (all patients)
2.3. call to PCI time (STEMI)
2.4. call to computed tomography time (stroke)
2.5. call to thrombolysis time (stroke)
All time intervals are measured with the computer system of the EMS dispatch centre and the computer systems of the hospitals. Both are synchronised.
3. improved patient safety and patient outcome
3.1. documentation of critical events, evaluated with medical records
3.2. length of hospital stay, evaluated with medical records
3.3. mortality, evaluated with medical records
4. Improved choice of appropriate hospital respiratory facility
comparison of the diagnosis and the level of the receiving hospital, evaluated with medical records
5. Improved quality of pre-hospital diagnosis
comparison between diagnosis in EMS and the diagnosis in hospital, evaluated with medical records
6. Improved quality of documentation in respect of medical and research purposes.
comparison between data quality in standard EMS (paper based documentation) and EMS with TMA (electronic documentation with integrated plausibility check)

Secondary outcome measures

The usability and feasibility of the system as well as the percentage of safe transferability of monitoring data will be observed and used for further improvement of the system. These criteria are measured with predefined checklists, which have to been completed after each mission with TMA.

Overall study start date
01/05/2010

Completion date
30/09/2010

Eligibility

Key inclusion criteria
All patients who calls EMS in Aachen, Germany from May 1st to September 30th 2010 (as of 17 /05/2011; March 1st to July 31st 2010 at time of registration)

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
1000 patients (500 study group, 500 control group)

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/05/2010

Date of final enrolment
30/09/2010

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital Aachen, Department of Anaesthesiology
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Sponsor information

Organisation
University Hospital Aachen (Germany)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.anaesthesie.ukaachen.de

ROR
https://ror.org/02gm5zw39

Funder(s)

Funder type
Government

Funder Name
Joint funding (Project-No.: 01MB07022)

Funder Name
German Federal Ministry of Economics and Technology (BMWi) (Germany)

Funder Name
German Aerospace Centre (DLR) (Germany)

Funder Name
Technical support and funding:

Funder Name
P3 Communications Engineering Company (Germany)

Funder Name
Philips Healthcare (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results of pilot study	01/02/2012		Yes	No