

New mobile application reduces the time lost in patients with a heart attack

Submission date 11/03/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/05/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/05/2018	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

There is specific type of heart attack, called STEMI, which requires immediate medical help. The special procedure called primary PCI, which aims to quickly restore blood flow and function, can remarkably improve prognosis and even save the life of the patient. Time interval to the procedure is crucial.

A new smartphone based communication technology enables an ECG transmission (test to check the heart's rhythm and electrical activity) to be sent by paramedics in the field to doctors in the specialised centre. They can remotely confirm the STEMI diagnosis so the patient is transferred directly to the lab where PCI procedure can be performed within recommended time interval. This study aims to compare two periods, the first from 2015 when communication technology is not used by paramedics and second from 2016, when all emergency service vehicles in the area are equipped with the technology.

Who can participate?

Adults suffering from chest pain

What does the study involve?

Participants suffering from chest pain are responded to by the emergency services. Paramedics responding to those in the first time period (2015) did not use any smartphone technology so participants receive treatment as normal.

When responding to participants in the second time period (2016) paramedics use smart phone technology to communicate with the doctors at the hospital. This allows quicker delivery of patients to the appropriate treatment location.

What are the possible benefits and risks of participating?

Participants may benefit from direct transfer to the necessary location, so decreased time lost and improved prognosis. There are no direct risks for patients as the study is observational.

Where is the study run from?

Teaching Hospital of J. A. Reiman (Slovakia)

When is the study starting and how long is it expected to run for?

May 2016 – September 2017

Who is funding the study?

Presov University (Slovakia)

Who is the main contact?

Dr Martin Studencan (Scientific)

Contact information

Type(s)

Scientific

Contact name

Dr Martin Studencan

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Contact details

Teaching Hospital of J.A.Reiman

Cardiology Clinic

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Slovakia

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

appSTEMI trial

Study information

Scientific Title

Significant benefits of new communication technology for time delay management in STEMI patients.

Study objectives

Use of the smartphone telemedicine to facilitate prehospital diagnosis of myocardial infarction (STEMI) could improve total ischemic period and prognosis of patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval not required: retrospective observational study, only anonymous data analysis and reporting. No medication but standard medical care was applied. Use of new communication technology has been used.

Study design

Longitudinal case series observational single centre study

Primary study design

Observational

Secondary study design

Case series

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available.

Health condition(s) or problem(s) studied

ST-elevation myocardial infarction (STEMI)

Interventions

Paramedics in the field spend 2 months responding to chest pain calls using no remote ECG evaluation and medical treatment as normal. They then spend 5 months responding to calls of chest pain, using smartphone technology to communicate with specialists in the local cardiocentre, aiming to evaluate the ECG and establish a diagnosis of STEMI remotely. If this is confirmed, they arrange primary transportation of the patient to the cathlab.

Intervention Type

Procedure/Surgery

Primary outcome measure

1. Total ischemic period measured using time interval between symptom onset (according to the patient, stated in medical records) and time of PCI procedure (moment of PCI wire insertion) stated in medical records by cardiologist performing the procedure.
2. Proportion of unwanted secondary transportation calculated using information from medical records. The number of STEMI patients transported to the cardiocentre by EMS via secondary transportations is compared to the number of all STEMI patients.

Secondary outcome measures

Technological reliability of the communication technology is assessed by measurement of an ECG transmission time. If the transmission fails or if it overcame 3 minutes – it is considered to be unsuccessful. Transmission within 3 minutes is considered to be successful.

Overall study start date

10/05/2016

Completion date

12/09/2017

Eligibility

Key inclusion criteria

1. Adult age 45 - 86
2. Suffering from chest pain
3. Visited by EMS staff once ECG has been recorded and suspicion raised about STEMI

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

160 patient of the analysed group from 2016 compared to 60 patients of the reference group from 2015

Key exclusion criteria

No specified exclusion criteria.

Date of first enrolment

01/08/2016

Date of final enrolment

31/12/2016

Locations

Countries of recruitment

Slovakia

Study participating centre

Teaching Hospital of J. A. Reiman, Cardiology Clinic

Holleho 14

Presov

Slovakia

08001

Sponsor information

Organisation

Presov University, Faculty of Health Care

Sponsor details

Partizanska 1
Presov
Slovakia
08001

Sponsor type

University/education

ROR

<https://ror.org/02ndfsn03>

Funder(s)

Funder type

University/education

Funder Name

Presov University

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

15/05/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request, once the study is published up to six months, from the first author ass.prof.Martin Studencan, M.D.,PhD., email adress studencan@fnspapresov.sk

It relates to anonymised data showing recorded clinical time intervals, gender, age, ejection fraction, ECG transmission time and yes/no final STEMI diagnosis confirmation.

IPD sharing plan summary

Available on request