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Regional integration between a cardiac centre and a referring hospital

Submission date	Recruitment status	[_] Prospectively registered
24/09/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/10/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/10/2020	Circulatory System	

Plain English summary of protocol

Background and study aims
Intensifying collaboration between hospitals may result in improved health care and better value for patients. The aim of our study is to evaluate clinical outcomes, patient satisfaction, and process and structure, as a result of setting up a regional integrated care delivery system between two hospitals.

Who can participate?
Adult heart patients diagnosed with coronary artery disease and treated by a coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI) in the Catharina Hospital (The Netherlands).

What does the study involve?
First, we will include the data of all patients diagnosed with coronary artery disease referred from other hospitals to Catharina Cardiac Centre and back for an heart intervention (i.e., CABG or PCI) between 2011 and 2016. This will be sub-divided into patients referred from the hospital 'SJG Weert' and patients referred from all other to the Catharina Cardiac Centre referring hospitals. We compared data of patients who were treated before the year 2014 with patients who were treated after the implementation of different interventions, e.g. modifications of patient brochures and the implementation of a new protocol for patients' discharge.
Secondly, patients referred from the hospital 'SJG Weert' to Catharina Cardiac Centre in the year 2013 and in the period January until September 2015 were included. This group received questionnaires delivered by post to assess patient satisfaction.

What are the possible benefits and risks of participating?
There are no immediate direct benefits to those taking part; however, there should be benefits to future heart patients and to the country's hospitals, because the results of the study are likely to influence patient value and lead to improvement of quality of care. There are no known risks to participants taking part in this study.

Where is the study run from?
Catharina Hospital in Eindhoven in collaboration with the hospital "SJG Weert" (The Netherlands)

When is the study starting and how long is it expected to run for?
January 2011 to December 2018

Who is funding the study?
Catharina Ziekenhuis (Catharina Hospital) (The Netherlands)

Who is the main contact?
Dennis van Veghel
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Contact information

Type(s)
Scientific

Contact name
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Michelangelolaan 2
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Enhancing regional integration between a cardiac centre and a referring hospital by focusing on clinical outcomes, patient satisfaction, and process and structure measures

Acronym
Regional integration

Study objectives
Setting up a regional integrated care delivery system will have a positive effect on quality improvement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
We submitted the study to our local ethics committee who judged that further elaboration of the protocol was not necessary since ethical approval is not required

Study design
Interventional multi-centre non-randomised retrospective survey study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Coronary artery disease (CAD)

Interventions
In 2014, different interventions were implemented in both hospitals included in the study (Catharina Cardiac Centre and SJG Weert), such as modification of patient brochures, implementation of a new protocol for patients' discharge, introduction of daily discussion sessions regarding hospitalized patients, organization of multidisciplinary meetings to discuss complex patients, increase of consultant capacity, modifications of planning and introduction of "time-outs" in the catheterization lab. All these potential improvement actions are still operational/being applied. For the follow-up measurements, data of patients treated in the year 2014 and later are used for assessing effects on clinical outcomes, patient satisfaction, and process and structure measures.

Intervention Type
Other

Primary outcome measure
Primary outcome measures 1-4 were assessed from electronic health records and cardiac databases of both hospitals within 30 days after the interventions:
1. Mortality
2. Deep sternal wound infection (DSWI)
3. Surgical re-exploration
4. Myocardial infarction
5. 120 day mortality, assessed from electronic health records and cardiac databases of both hospitals 120 days after the interventions
6. Urgent coronary artery bypass graft (CABG) within 24 hours, assessed from the electronic health records of the Catharina Cardiac Centre

7. Cerebrovascular accidents (CVA) within 72 hours, assessed from the electronic health records of the Catharina Cardiac Centre

Secondary outcome measures
1. Degree of patient satisfaction, assessed several months after patients were treated in the heart centre (this differs between each patient, ranging from 14 days to 5 months after treatment) using self-administered questionnaires, consisting of 28 items regarding:
1.1. Communication with the hospital (2 items)
1.2. Communication between the hospitals and the patient's general practitioner (2 items)
1.3. Education and education material (4 items)
1.4. Consistency and compatibility between the two hospitals (2 items)
1.5. Access time (2 items)
1.6. Quality of care (4 items)
1.7. Unexpected events and complications (3 items)
1.8. Hospital stay (4 items)
1.9. Personal contact with physician in both hospitals (2 items)
1.10. An overall grade from 1-10
2. Process and structure, regarding the following, assessed using indicators commonly used in quality inspections by the Dutch Association of Cardiologists (NVVC) and European Society of Cardiology (ESC) (such as the KISZ survey of the Dutch Association of Internists and standard operating procedures), before (in 2013) and after (in 2015) the implementation of the interventions:
2.1. Organisation
2.2. Cooperation
2.3. Outpatient clinic
2.4. Echo and ergometry
2.5. Coronary care unit
2.6. Cardiac catheterisation lab

Overall study start date
01/08/2012

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Aged 18 years and older
2. Diagnosed with coronary artery disease
3. Referred from other hospitals to Catharina Cardiac Centre and back for coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI) between 2011 and 2016 AND/OR referred from the hospital SJG Weert to Catharina Cardiac Centre in the year 2013 and in the period January until September 2015

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
12,000

Key exclusion criteria
1. Treated with combined treatments, such as aortic valve replacement in combination with CABG
2. Not referred from another hospital

Date of first enrolment
01/05/2017

Date of final enrolment
01/10/2017

Locations

Countries of recruitment
Netherlands

Study participating centre
Catharina Ziekenhuis
Michelangelolaan 2
Eindhoven
Netherlands
5623 EJ

Study participating centre
SJG Weert
Vogelsbleek 5
Weert
Netherlands
6001 BE

Sponsor information

Organisation
Catharina Ziekenhuis

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01qavk531

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact, peer-reviewed journal

Intention to publish date
01/11/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the privacy of our participants (patients).

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		26/09/2018	02/04/2019	No	Yes
Results article	results	03/06/2020	26/10/2020	Yes	No