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Nurse-led follow-up care for patient relatives at risk for cardiomyopathy

Submission date
14/04/2016

Recruitment status
No longer recruiting

Registration date
23/04/2016

Overall study status
Completed

Last Edited
09/08/2019

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cardiomyopathy is a long term disease that affects the heart muscle. It involves the muscle walls of the heart have become stretched and thin so they are no longer effective at pumping blood around the body. It is an inherited (genetic) condition, which means that people are more likely to develop it if their parents are affected. Increasing numbers of relatives of people with cardiomyopathy are being identified and followed up by cardiologists so that preventative action and treatment can be started, however given limited health care resources, good quality low cost alternative approaches are needed. This study is going to look at the effectiveness of cardiogenetics clinic (CGC) appointments led by a genetic counsellor with a nursing background, in which relatives have their DNA tested to find out if they will develop the condition. The aim of this study is to compare how many people take up CGC appointments compared to normal care, and compare the resources the two consultations use.

Who can participate?
Healthy adults aged between 18 and 40 who have a normal UK diet, including 'junk food' at least once per week.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive cardiogenetics clinic (CGC) appointments with a cardiogenetics councillor. During the consultations, medical history and risks of developing a heart condition are discussed, and DNA samples are taken to find out if the participant is genetically predisposed to developing a heart condition. Those in the second group receive a standard follow up appointment with a cardiologist only in which they receive general assessments testing for a heart problem such as a heart scan and blood pressure meaasurements. After each consultation for the one and a half years of the study, amount of relatives who attend the appointments and their satisfaction with the appointments are measured.

What are the possible benefits and risks of participating?
There is a possibility that participants could benefit from improved health and be less likely to develop a heart condition. There are no direct risks involved to those taking part.

Where is the study run from?
1. University Medical Center Groningen (Netherlands)
2. Antonius Ziekenhuis, Sneek (Netherlands)

When is the study starting and how long is it expected to run for?
September 2015 to March 2016

Who is funding the study?
University Medical Center Groningen (Netherlands)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Follow-up care by a specialized genetic counsellor for patient relatives at risk for cardiomyopathies is cost-saving and well-appreciated: a randomised comparison

Study objectives
Quality of cardiological care, satisfaction and PPC is at least comparable between the cardiological and genetic counsellor/nurse-led follow-up care and costs are lower at the Cardiogenetic clinc.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The UMCG Medical Ethical Review Committee declared this study to be exempt from formal review and approval (M11.108973)

Study design
Open-label randomized comparison of two different follow-up care modalities for first-degree relatives of index patients at risk for inherited cardiomyopathy

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Cardiomyopathy

Interventions
First-degree relatives of index patients not already known to have a DCM/HCM diagnosis (based on their first screening at a combined Cardiogenetics Clinic), but who are eligible for follow-up according to information from the local patient database, are randomly assigned (1:1) at the beginning of the study and stratified by one of the hospitals to receive one of two care models:

Group 1: Participants receive a cardiogenetics clinic (CGC) appointment. This involves being invited to an appointment and seen by a genetic counsellor. Family history, reproductive options and new diagnostic /treatment options or the results of DNA testing when appropriate, and encouragement for other relatives to have genetic or cardiologic screening are discussed. If the participants consented to predictive DNA testing, the genetic counsellor initiated this procedure immediately after the counselling session. If the genetic counsellor proposed further tests this is discussed immediately (in another room) with the supervising cardiologist (multidisciplinary context) and, in a joint consultation, additional diagnostics were discussed with the patient. The cardiologist later discussed the results of additional diagnostic tests with the participant.

Group 2: Participants receive regular follow-up care by a cardiologist

Follow up for all participants involves ECG, echocardiography, measurement of blood pressure, assessment of the patient and his or her family's health and, as needed, providing information on DCM/HCM. Guided by the results of the cardiology investigations, according to the protocols and/or the patient/family history, further tests such as a Holter monitor, an exercise stress test or a cardiac MRI took place

Intervention Type
Other

Primary outcome(s)
1. Uptake percentage of follow-up by relatives at either clinic during the study is measured using patient records following each consultation for 1.5 years
2. Perceived Personal Control (PPC) and patient satisfaction are determined using questionnaires following each consultation for 1.5 years
3. Results of supervision (like additional diagnostics, referral to cardiologist, wrong conclusions) are determined using patient records following each consultation for 1.5 years

4. Resource use and cost reductions are determined using patient records after the consult and personnel/ hospital information at 1.5 years

Key secondary outcome(s))
N/A

Completion date
01/04/2013

Eligibility

Key inclusion criteria
1. Aged > 16 years
2. Relative of patients with DCM/ HCM or mutation carriers
3. Participants must be either:
3.1. Carriers of mutations in the LMNA, DES or PLN genes, who are at a higher prior risk for malignant ventricular arrhythmias compared to other groups; or
3.2. Phenotype-negative relatives (over 16 years of age) of index patients with DCM or HCM with a proven pathogenic mutation and therefore at risk for developing DCM or HCM; or
3.3. Phenotype-negative relatives of index patients with potentially inherited DCM or HCM in whom no pathogenic mutation had been identified

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
189

Key exclusion criteria
1. Any signs or symptoms of the disease
2. Presence of other heart diseases
3. A medical history with complex co-morbidity

Date of first enrolment
01/08/2011

Date of final enrolment
01/10/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen
Hanzeplein 1
Groningen
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Study participating centre
Antonius Ziekenhuis Sneek
Bolswarderbaan 1
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8601 ZK

Sponsor information

Organisation
University Medical Center Groningen (Netherlands)

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universitair Medisch Centrum Groningen

Alternative Name(s)
University Medical Center Groningen, UMCG

Funding Body Type
Government organisation

Funding Body Subtype

Local government

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2017	09/08/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes