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Efficacy of an exercise training programme for patients with ischaemic cardiopathy

Submission date
21/04/2010

Recruitment status
No longer recruiting

Registration date
27/05/2010

Overall study status
Completed

Last Edited
11/04/2018

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Cardiovascular (heart) disease (CVD) is a health problem of the first order all over the world. In Europe, CVD is the leading cause of death and has a huge impact on the health budget. Myocardial ischemia (MI) occurs when blood flow to the heart is reduced, preventing it from receiving enough oxygen. Survival rates after MI have increased in recent years, and a large number of MI survivors are discharged from the hospital into the community and are at a high risk of readmission. Cardiac rehabilitation programmes (CRPs) provide regular secondary prevention therapies and assessments by a team of professionals who offer continued education and resolve patients' doubts during the period after a MI. CRPs decrease mortality and the risk of recurrent MI, promote a healthy lifestyle and improve functional capacity among patients with coronary heart disease. Most studies on post-MI survival, readmissions and physical rehabilitation agree that physical exercise reduces mortality, but its impact on readmissions has not been conclusively established. While many studies have found no differences in readmissions after CRP, others report that CRPs reduced cardiac readmission rates (by between 17% and 79%). Moreover, the few studies available on the issue do not focus on identifying the best exercise regimens for reducing readmissions. Evidence that these programmes reduce readmission would provide an additional incentive for hospitals and providers to refer their patients to a CRP after a MI. The aim of this study is to assess the effectiveness of a supervised exercise training programme for reducing cardiac readmissions in patients with MI in the first year after hospital discharge.

Who can participate?
Patients aged over 18 with MI

What does the study involve?
Participants are randomly allocated either to a control group to receive standard care, or to an intervention group which, in addition to standard care, takes part in a supervised exercise training program consisting of three hours a week (spread over three alternate days) of supervised exercise training for 10 weeks. Both groups undergo an exercise stress test and a blood test during the first and third month after hospital discharge. The study also explores differences between groups in readmission, death, hospital emergency visits, functional capacity, quality of life, adherence to cardiac pharmacological treatment, attendance at nurse

follow-up visits, satisfaction with care received, and return to work. The follow-up period is 12 months after hospital discharge.

What are the possible benefits and risks of participating?
Reducing cardiac readmissions and improving quality of life and functional status of the patient accelerate return to normal life and shorten recovery time. In addition, during admission and follow-up, the patient and family receive detailed information on lifestyle habits, physical exercise and aspects to consider in order to favour active control of the disease by the patient and to increase safety, both highly important factors for reducing the number of readmissions. From the standpoint of health planning and management, the findings of the study may entail substantial savings in the budgets of health services in the country, reducing readmissions and the total length of hospitalization in a disease as frequent as MI. Thus, this study may encourage the use of supervised exercise training programs in CRP. The intervention is not overly complex and can be performed easily by well-trained health professionals, and could be widely applied.

Where is the study run from?
Althaia, Xarxa Assistencial Universitària de Manresa (Spain)

When is the study starting and how long is it expected to run for?
May 2010 to December 2018

Who is funding the study?
Fundació Althaia (Spain) - Xarxa Assistencial Universitària de Manresa

Who is the main contact?
Dr Núria Santaularia Capdevila

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R01/08-09

Study information

Scientific Title
Randomised hospital-based clinical trial on the efficacy of an exercise training programme versus care as usual for adult patients with ischaemic cardiopathy

Study objectives
Primary hypothesis:
Cardiac rehabilitation programmes decrease the number of hospital readmissions of patients diagnosed of ischaemic cardiopathy.

Secondary hypotheses:
1. Patients with ischaemic cardiopathy who join a cardiac rehabilitation programme obtain a better functional capacity than patients who receive the usual therapy
2. Health-related quality of life is better in patients who enrol in a cardiac rehabilitation programme than in those who receive the usual therapy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comitè Ètic dInvestigació Clínica de la Fundació Unió Catalana dHospitals, 30/06/2009, ref: CEIC 09/38

Study design
Open randomised single-centre hospital-based clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Ischaemic cardiopathy

Interventions

Control group:
Patients will receive the usual therapy of our hospital. Hospitalised patients will be instructed to do exercises to regain mobility in order to maintain and improve muscular tone and peripheral circulation. They will be instructed on how to return to physical activity and receive information on cardiovascular risk factors. Written information will be provided.

After hospital discharge, patients will undergo a physical strength test at 15 days and at 3 months and will have ambulatory follow-up with a nurse at 15 days, 3, 6 and 12 months from hospital discharge in order to control the risk factors and review adherence to medication. During these visits, various tests will be administered and control blood tests will be performed.

Intervention group:
The intervention will consist of a physical training programme, personalised according to the results of the physical strength test performed 15 days after discharge. The programme consists of 3 hours a week of supervised training during 10 weeks. The following activities will be performed: initial warm-up, muscle stretching, aerobic exercises (cycloergometer and/or treadmill), isometric exercises of upper and lower extremities, relaxation exercises, breathing techniques and final cooling. Moreover, instructions will be given on self-pulse counting, subjective perception of effort using Börg scale, postural health and minimizing physical effort.

After hospital discharge, the patients will undergo a physical strength test at 15 days and at 3 months and will have ambulatory follow-ups with a nurse at 15 days, 3, 6 and 12 months from hospital discharge in order to control risk factors and assess adherence to medication. During these visits, various tests will be administered and control blood tests will be performed.

Intervention Type

Behavioural

Primary outcome measure

1. Number of admissions for any reason during period of follow-up, measured at 15 days, 3, 6 and 12 months
2. Number of admissions with main cardiac diagnosis at discharge during period of follow-up, measured at 15 days, 3, 6 and 12 months
3. Time from first admission, measured at 15 days, 3, 6 and 12 months
4. Percentage of patients readmitted during period of follow-up, measured at 15 days, 3, 6 and 12 months
5. Total days of hospitalisation for any reason during period of follow-up, measured at 15 days, 3, 6 and 12 months
6. Total days of hospitalisation for cardiac event during period of follow-up, measured at 15 days, 3, 6 and 12 months
7. Functional status according to physical strength test, measured at 15 days and at 3 months
8. Mortality, measured at 15 days, 3, 6 and 12 months

Added 21/03/2018:
All outcomes are also measured at 5 years

Secondary outcome measures

Initial outcomes at time of registration:
1. Adherence to cardiac rehabilitation programme, according to attendance to follow-up visits and training sessions, measured at 15 days, 3, 6 and 12 months

2. Adherence to medication, according Haynes-Sackett test, measured at 15 days, 3, 6 and 12 months
3. Quality of life, assessed using SF-36 test at 15 days, 3 and 12 months from hospital discharge
4. Degree of patients' satisfaction with assistance received. The Ambulatory Specialised Care 2008 questionnaire of Servei Català de la Salut will be used; questions selected from the questionnaire on satisfaction of policy holders of CatSalut for services offered: Ambulatory Specialised Care 2008. This will be administered 12 months after hospital discharge

As of 24/06/2010 point 3 has been amended as follows:
3. Quality of life, assessed using EuroQoL test (Spanish version) at 15 days, 3 and 12 months from hospital discharge

Added 21/03/2018:
1. All-cause hospital emergency visits, assessed at 12 months and 5 years of follow-up
2. Functional status according to Caspersen & Powell classification and IPAQ questionnaire, assessed at 5 years of follow-up.
3. Return to work, assessed at 12 months and 5 years of follow-up
Adherence to medication and quality of life also assessed as above at 5 years of follow-up

Overall study start date
10/05/2010

Completion date
30/12/2018

Eligibility

Key inclusion criteria
1. Patients over 18 years old (either sex), autonomous and able to take decisions, who accept to participate in the study
2. Patients diagnosed with ischaemic cardiopathy admitted to the Cardiology Service at our centre
3. Patients without cognitive deficit, able to follow the cardiac rehabilitation programme
4. Patients with cardiopathy, residing in the service area of Althaia

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
292 patients (146 patients in each group)

Key exclusion criteria

1. Patients under 18 years old
2. Patients with symptoms of cor pulmonale
3. Patients with additional diagnosis affecting prognosis of cardiac disease
4. Patients with dyspnoea caused by severe pulmonary pathology
5. Patients with cardiopathy residing outside the service area of Althaia
6. Patients who do not accept to participate in the study

Date of first enrolment
01/06/2010

Date of final enrolment
19/06/2012

Locations

Countries of recruitment
Spain

Study participating centre
Althaia, Xarxa Assistencial Universitària de Manresa
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Sponsor information

Organisation
Fundació Althaia (Spain) - Xarxa Assistencial Universitària de Manresa

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Sponsor type
Research organisation

Website
http://www.althaia.cat/

ROR
https://ror.org/00bxg8434

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Fundació Althaia (Spain) - Xarxa Assistencial Universitària de Manresa

Funder Name
College of Physiotherapists of Catalonia (Collegi de Fisioterapeutes de Catalunya) (Spain)

Funder Name
Departament de Salut. Acció instrumental d'intensificació de professionals de la Salut en fisioteràpia (SLT006/17/00186).

Results and Publications

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

Intention to publish date
30/12/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/04/2013		Yes	No
Results article	results	01/03/2017		Yes	No