ISRCTN87465420 https://doi.org/10.1186/ISRCTN87465420

Quality of adherence to guideline recommendations for life-saving treatment in heart failure: an international survey

Submission date
05/02/2015

Recruitment status
No longer recruiting

Registration date
07/05/2015

Overall study status
Completed

Last Edited
14/06/2023

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Heart failure (HF) is associated with a high mortality and morbidity, reduced quality of life, and increasing health care costs in Europe as well as across the world. The prescription of evidence-based therapies recommended by guidelines is the most effective way of ensuring that patients receive high-quality and optimal care. Surveys of patients with HF often provide descriptions of the clinical characteristics and management of patients and of outcomes, but we lack data on the use of guideline-recommended therapies in all potentially eligible patients. This is the aim of this study.

Who can participate?
Adult outpatients with chronic HF and left ventricular systolic dysfunction (LVSD).

What does the study involve?
Physician selection is based on the best available sources, either local or regional, concerning the epidemiology and medical care data, including available market data and epidemiological surveys. A general target of 10-20 consecutive patients per investigator was used ensuring the best possible representative inclusion of the HF population in each practice setting.
Information collected includes: demographics; medical history; risk factors and lifestyle; results of physical examination; current symptoms; laboratory values if available; and current medical treatments. Adherence to evidence-based pharmacologic treatments recommended by guidelines will be determined by calculating the adherence score, taking into account the treatment eligibility criteria and the existence of contraindications to drugs based on the international guidelines on management of HF.

What are the possible benefits and risks of participating?
This information is expected to be important to physicians, care providers, and health services, by identifying gaps between evidence and practice and areas for improvement in the post-discharge care of outpatients with chronic HF and LVSD. Physicians have been instructed to continue management and treatment of patients according to their usual practice and the new international guidelines for the management of HF. No specific tests or therapies will be

prescribed as part of this survey, and the management of patients will be completely left to the discretion of participating physicians.

Where is the study run from?
547 centres from 36 countries

When is the study starting and how long is it expected to run for?
January 2013 to September 2018

Who is funding the study?
Servier (France)

Who is the main contact?
Professor Michel Komajda

Contact information

Type(s)
Scientific

Contact name
Dr Michel Komajda

Contact details
Groupe Hospitalier Pitie - Salpetriere
Département de Cardiologie
47/83 boulevard de l'Hôpital
Paris
France
75013

Additional identifiers

Study information

Scientific Title
QUAlity of adherence to guideline recommendations for LIfe-saving treatment in heart failure: an international surveY: an observational study

Acronym
QUALIfY

Study objectives
1. Assess clinical characteristics and management of outpatients with heart failure
2. Focus on how monitoring of disease status can be used to guide treatment
3. Evaluate the prescription of recommended therapeutic options in eligible patients
4. Assess adherence to the new European Society of Cardiology guidelines for the management of heart failure

Ethics approval required

Old ethics approval format

Ethics approval(s)
Ethics approval obtained in every country in accordance with local regulations. All 557 centres obtained ethics approval before recruitment of the first participant (the first approval was obtained on 10/06/2013 from the Ethics Committee at the National Institute of Cardiovascular Diseases, Slovakia; approval for the last site was on 20/09/2014 from McGill University Health Centre Biomedical D, Canada).

Primary study design
Observational

Study design
Prospective observational longitudinal survey

Study type(s)
Other

Health condition(s) or problem(s) studied
Heart failure

Interventions
Non-interventional survey

Intervention Type
Other

Primary outcome(s)
1 To evaluate physician’s adherence to HF guidelines by measuring prescriptions modalities of recommended HF medications
2. To calculate an adherence score
3. To analyze the reasons for non-adherence
4. To assess the impact of adherence level on clinical outcomes

Measured at baseline and at 6, 12 and 18 months.

Key secondary outcome(s)
To characterize the clinical characteristics and management of outpatients with HF and left ventricular systolic dysfunction (LVSD).

Measured at baseline and at 6, 12 and 18 months.

Completion date
01/09/2018

Eligibility

Key inclusion criteria
Outpatients with chronic heart failure:
1. > 18 years of age

2. Hospitalised for worsening of heart failure within 1–15 months
3. With LVSD as demonstrated by left ventricular ejection fraction ≤ 40% measured using the most recent echocardiogram (≤ 2 years)
4. Validation of rhythm at inclusion

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patients on waiting list for heart transplantation or planned implantation of left ventricular assist device; planned cardiac resynchronisation therapy and implantable cardioverter defibrillators are permitted
2. Patients with planned revascularisation
3. Patients hospitalised for cardiovascular disease within the past 4 weeks
4. Conditions hampering participation or the 18-month follow-up

Date of first enrolment
01/09/2013

Date of final enrolment
30/12/2014

Locations

Countries of recruitment
Armenia

Australia

Austria

Azerbaijan

Bahrain

Belarus

Brunei Darussalam

Canada

China

Denmark

Egypt

Georgia

Germany

Greece

Hungary

Ireland

Jordan

Kazakhstan

Korea, South

Kuwait

Lebanon

Lithuania

Malaysia

Morocco

Oman

Poland

Portugal

Qatar

Romania

Russian Federation

Slovakia

Spain

Thailand

Türkiye

Ukraine

United Arab Emirates

Study participating centre
547 from 36 countries
France
-

Sponsor information

Organisation
Servier

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
Servier (France)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2016		Yes	No
Results article		10/02/2021	14/06/2023	Yes	No
Results article		30/04/2017	14/06/2023	Yes	No

Study website	Study website	11/11/2025	11/11/2025	No	Yes