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Older heart failure patients initiated on ivabradine in the UK: Quality of life

Submission date 07/11/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/11/2013	**Overall study status** Completed	
Last Edited 06/09/2018	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
1-2% of the UK population have heart failure, which accounts for around 900,000 people in the UK. The main aims of heart failure treatment include reducing symptoms, improving levels of activity, reducing the number of hospital visits and improving how patients feel (quality of life). This study is focused on a group of older people in the UK who have recently been started on a treatment with a drug called ivabradine for heart failure. This study aims to examine their quality of life over a period of time after starting the treatment.

Who can participate?
People aged at least 70 years, who have heart failure and who have been started on ivabradine medication for their heart failure by their doctor can participate in this study.

What does the study involve?
Patients will see their doctor as usual and complete two short questionnaires to assess their quality of life. Their doctor will record their heart rate and blood pressure, and conduct a walking test where applicable, on entry to the study, after two months and then again after four months. These tests and questions are carried out as part of normal care. Patients will be followed up for around 6 months.

What are the possible benefits and risks of participating?
There are no direct benefits expected from being involved in the research, although the results could be used to improve patient care in future. There are no additional risks of participating as usual clinical care continues throughout the study. The risks of personal data being disclosed are slight as only encrypted anonymised data will leave NHS premises.

Where is the study run from?
The study is run from about 50 UK sites (including general practices and hospital outpatient departments).

When is study starting and how long is it expected to run for?
The study will start in January 2014 and is expected to run until August 2014.

Who is funding the study?
Servier Laboratories Ltd (UK)

Who is the main contact?
Medical Information - Servier
01753 666409
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Contact information

Type(s)
Scientific

Contact name
Dr Paul Kalra

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IC416257001GBR

Study information

Scientific Title
LIVE:LIFE - OLder heart failure patients Initiated on iVabradinE in UK quaLIty of liFE

Acronym
LIVE:LIFE

Study objectives
The hypothesis is that we will see an improvement in the quality of life, i.e. a greater than 20% reduction of the baseline Minnesota Living With Heart Failure Scores (lower scores meaning a better quality of life).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES North East Newcastle and North Tyneside 2, 13/11/2013, ref: 13/NE/0345

Study design
Multicentre longitudinal observational single-cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
GP practice

Study type(s)
Quality of life

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
Heart failure with left ventricular systolic dysfunction

Interventions
This is an observational study so clinical care will continue as usual.
At baseline, at two months and at six months:
1. Heart rate, blood pressure and 6-minute walk test (where offered) will be recorded
2. Responses to the Minnesota Living With Heart Failure Questionnaire and SF12 questionaire will be used to formally assess quality of life

After a further 12 months (i.e. at 18 months from baseline) data about patients' medications (i.e. doses and total number) will be collected from their medical records.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Change in total score from the Minnesota Living with Heart Failure Questionnaire at six months. The change from baseline will be evaluated using the paired t-test.

Secondary outcome measures
1. Change in 6-minute walking test data at six months is the key secondary outcome measure. The change from baseline will be evaluated using the paired t-test

2. The numbers of patients experiencing clinically significant changes (defined as a change of 5 units or more from baseline) in the Minnesota Living With Heart Failure Questionnaire will also be assessed

Overall study start date
01/01/2014

Completion date
10/11/2016

Eligibility

Key inclusion criteria
Heart failure patients:
1. Aged 70 years or older
2. Where a decision has already been made to initiate ivabradine for treatment of HF as per licensed indication for heart failure,
2.1. Chronic heart failure New York Heart Association (NYHA) Class II to IV with systolic dysfunction
2.1. In sinus rhythm with resting HR ≥75 beats per min
2.3. In combination with standard therapy including beta blockers or when beta blockers are contraindicated or not tolerated
3. Who have given their informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
220

Key exclusion criteria
1. Patients not receiving ivabradine as planned within 2 weeks from inclusion in the study
2. Patients no longer under the care of a study physician (named in the delegation log)
3. Patients enrolled or planning to be enrolled into an interventional clinical trial
4. Patients prescribed ivabradine in a manner not consistent with the Summary of Product Characteristics (SmPC) for congestive heart failure (CHF) with left ventricular systolic dysfunction (LVSD)
5. Patients with cognitive impairment to such a degree that the investigator feels they would be unable to complete the study

Date of first enrolment
01/01/2014

Date of final enrolment

31/03/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Alexandra Hospital
Southwick Hill Road
Portsmouth
United Kingdom
PO6 3LY

Sponsor information

Organisation
Servier Laboratories Ltd (UK)

Sponsor details
Sefton House
Sefton Park
Bells Hill
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SL2 4JS

Sponsor type
Industry

Website
http://www.servier.co.uk/

ROR
https://ror.org/02fbwdh31

Funder(s)

Funder type
Industry

Funder Name
Servier Laboratories Ltd (UK)

Results and Publications

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

Intention to publish date
31/10/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request. Requests should be made through the following website for the attention of the Medical Affairs Department (General enquiry): https://servier.co.uk/content/contact-us. As specified in the Study Protocol, anonymised patient-level data will be made available to the research community on reasonable request until November 2023, as a Microsoft Excel spreadsheet. Access to the study data will be at Servier's discretion as study Sponsors.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/12/2017		Yes	No
HRA research summary			28/06/2023	No	No