ISRCTN87590288 https://doi.org/10.1186/ISRCTN87590288

The effect of ivabradine on hemodynamics in patients with chronic heart failure

Submission date	Recruitment status	[ ] Prospectively registered
18/03/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/01/2012	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/01/2019	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Marie Lazarova

Contact details
Cardiology Department
Faculty Hospital Olomouc
I.P.Pavlova 6
Olomouc
Czech Republic
775 20

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Nil known

Study information

Scientific Title
The effect of ivabradine versus standard pharmacotherapy on hemodynamics in patients with chronic heart failure (CHF) and the analysis of the possible mechanism of improvement

Study objectives
Symptoms of CHF and hemodynamics (measured by echocardiogram [ECHO]) will be improved in CHF patients who receive ivabradine versus patients that receive standard pharmacotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Non-blinded prospective study

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic heart failure

Interventions
1. All the patients will be managed with standard CHF therapy: up-titrated beta-blocker dose, angiotensin-converting-enzyme (ACE) inhibitor dose, spironolacton dose
2. Adding diuretics, digoxin if indicated (according to the Czech cardiology association guidelines)
3. As well as non-pharmacologic treatment with Cardiac Resynchronization Therapy Device (CRT-D) according to the current guidelines of Czech cardiology association
4. The patients in the ivabradine group will in addition have the up-titrated dose of ivabradine to 7.5 mg twice daily, unless they have bradycardia

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ivabradine

Primary outcome measure
1. Improvement of quality of life
2. Peak oxygen consumption
3. New York Heart Association (NYHA) class improvement
4. Improvement in hemodynamics (measured in non-invasive way with echocardiography and MRI) in patients with CHF after recieving medication of ivabradine in addittion to standard optimized HF pharmacotherapy

Secondary outcome measures
Number of patients with good response to ivabradine therapy

Overall study start date
15/04/2011

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Aged more than 18 years
2. CHF
3. Left ventricular ejection fraction (LVEF) ≤ 40%
4. Sinus rhythm
5. Patients four weeks stabile on maximal tolerated standard CHF pharmacotherapy without acute decompensations
6. Heart rate after 5 minutes resting more than or 70 beats per min measured by ECG
7. Patients indicated to Cardiac Resynchronization Therapy (CRT) will be enrolled after 6 months after implantation
8. Patients who give written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30-50

Key exclusion criteria

1. Permanent atrial fibrillation with the rate control strategy
2. Sick sinus syndrome
3. Sinoatrial block or AV block of III degree without pacemaker
4. Patients with pacemaker/implantable cardioverter defibrillator (ICD) without CRT with more than 40% paced contractions daily
5. Patients less than two months after myocardial infarction (MI)
6. Ivabradine intolerance
7. Severe liver insufficiency
8. Combination with strong CYP3A4 inhibitors such as azol antimycotics (ketokonazol, itrakonazol), makrolid antibiotics (klarithromycin, erythromycin per os, josamycin, telithromycin), inhibitors of HIV proteases (nelfinavir, ritonavir) and nefazodon
9. Other illness which limits patients prognosis of less than two years
10. Women in fertile age without effective contraception
11. Breastfeeding women

Date of first enrolment
15/04/2011

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Czech Republic

Study participating centre
Cardiology Department
Olomouc
Czech Republic
775 20

Sponsor information

Organisation
Faculty Hospital Olomouc (Czech Republic)

Sponsor details
I.P. Pavlova 6
Olomouc
Czech Republic
775 20

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01jxtne23

Funder(s)

Funder type
University/education

Funder Name
Faculty Hospital Olomouc (Czech Republic)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration