

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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 receiving medication of ivabradine in addition to standard optimized HF pharmacotherapy

Key secondary outcome(s)

Number of patients with good response to ivabradine therapy

Completion date

31/12/2015

Eligibility

Key inclusion criteria

1. Aged more than 18 years
2. CHF
3. Left ventricular ejection fraction (LVEF) \leq 40%
4. Sinus rhythm
5. Patients four weeks stable 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

<https://ror.org/01jxtne23>

Funder(s)

Funder type

University/education

Funder Name

Faculty Hospital Olomouc (Czech Republic)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration