

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

<b>Submission date</b> 18/03/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 04/01/2012	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 25/01/2019	<b>Condition category</b> 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

**Contact name**  
Dr Marie Lazarova

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

## Additional identifiers

## 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