# Clinical trials of ivabradine

**TrialResults-center** www.trialresultscenter.org

## 1 stable angina

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **ivabradine 10mg vs placebo** | | | |
| Borer (CL2-009) 10mg , 2003<br>n=91/91<br>follow-up: 2 weeks | Ivabradine 5 mg twice daily (10mg/d)<br>versus<br>placebo | | double blind |
| **ivabradine 15mg vs placebo** | | | |
| BEAUTIFUL , 2008<br>[NCT00143507]<br>n=5479/5438<br>follow-up: 19 months (range 16-24) | ivabradine target dose of 75 mg twice a day<br>versus<br>placebo | patients with coronary artery disease and left-ventricular systolic dysfunction (LVEF <=40% ) | double blind<br>33 countries |
| **ivabradine 20mg vs placebo** | | | |
| SIGNIFY , 2014<br>[ISRCTN61576291]<br>n=9550/9552<br>follow-up: 27.8 mo (median) | ivabradine, at a dose of up to 10 mg twice daily, with the dose adjusted to achieve a target heart rate of 55 to 60 beats per minute.<br>versus<br>placebo | patients who had both stable coronary artery disease without clinical heart failure and a heart rate of 70 beats per minute or more | Parallel groups<br>double-blind |
| Borer (CL2-009) 20mg , 2003<br>n=88/91<br>follow-up: 2 weeks | ivabradine 10mg twice daily (20mg/d)<br>versus<br>placebo | | double blind |
| **ivabradine 5mg vs placebo** | | | |
| Borer (CL2-009) 5mg , 2003<br>n=90/91<br>follow-up: 2 weeks | - | - | Parallel groups<br>double blind |
| **ivabradine 15mg vs placebo (on top standard treatment)** | | | |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| BEAUTIFUL (angina subgroup)<br>n=734/773<br>follow-up: 19 months (range 16-24) | ivabradine target dose of 75 mg twice a day<br>versus<br>placebo | patients with stable coronary artery disease and left ventricular systolic dysfunction with limiting angina | double blind<br>33 countries |
| **ivabradine 10mg vs placebo on top of amlodipine** | | | |
| CL3-018 10mg , 3000<br>*unpublished*<br>n=232/252<br>follow-up: 12 weeks | ivabradine 5mg twice daily (10mg/d)<br>versus<br>placebo | - | Parallel groups |
| **ivabradine 15mg vs placebo on top of amlodipine** | | | |
| CL3-018 15mg , 3000<br>*unpublished*<br>n=244/252 | ivabradine 7.5mg twice daily (15mg/d)<br>versus<br>placebo | - | |
| **ivabradine 15mg vs placebo on top of atenolol** | | | |
| ASSOCIATE (Tardif) , 2009<br>[NCT00202566]<br>n=449/440<br>follow-up: 4 months | ivabradine 5 mg b.i.d. for 2 months, increased to 7.5 mg b.i.d. for a further 2 months (on top atenolol 50 mg/day )<br>versus<br>placebo on top atenolol 50 mg/day | patients with stable angina receiving atenolol 50 mg/day or another beta-blocker at equivalent doses for at least 3 months | Parallel groups<br>double blind<br>20 countries |
| **ivabradine vs amlodipine** | | | |
| CL3-023 (15mg)<br>*unpublished*<br>n=381/398<br>follow-up: 3 months | ivabradine 7.5mg twice daily<br>versus<br>amlodipine | | Parallel groups<br>double-blind |
| CL3-023 (20mg)<br>*unpublished*<br>n=376/398<br>follow-up: 3 months | ivabradine 10mg twice daily<br>versus<br>amlodipine | | double-blind |
| **ivabradine 15mg vs amlodipine** | | | |
| Ruzyllo (CL3-023) 15mg , 2007<br>n=400/404<br>follow-up: 3 months | ivabradine 7.5mg twice daily<br>versus<br>amlodipine 10mg once daily | Patients with a >/=3-month history of chronic, stable effort-induced angina | Parallel groups<br>double-blind |
| **ivabradine 20mg vs amlodipine** | | | |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| Ruzyllo (CL3-023) 20mg , 2007<br>n=391/404<br>follow-up: 3 months | ivabradine 10mg twice daily<br>versus<br>amlodipine 10mg once daily | Patients with a >/=3-month history of chronic, stable effort-induced angina | Parallel groups<br>double-blind |
| **ivabradine 15mg vs atenolol** | | | |
| INITIATIVE (CL3-017, Tardif) 15mg , 2005<br>n=315/307<br>follow-up: 16 weeks | ivabradine 5 mg bid for 4 weeks and then either 7.5 or 10 mg bid for 12 weeks<br>versus<br>atenolol 50 mg od for 4 weeks and then 100 mg od for 12 weeks | patients with stable angina | double-blind |
| **ivabradine 20mg vs atenolol** | | | |
| INITIATIVE (CL3-017, Tardif) 20mg , 2005<br>n=317/307<br>follow-up: 16 weeks | ivabradine 5 mg bid for 4 weeks and then 10 mg bid for 12 weeks<br>versus<br>atenolol 50 mg od for 4 weeks and then 100 mg od for 12 weeks | patients with stable angina | Parallel groups<br>double-blind |



More details and results :

- HR-slowing agents for stable angina in patients with left ventricular dysfunction at http://www.trialresultscenter.org/go-Q118
- HR-slowing agents for stable angina in all type of patients at http://www.trialresultscenter.org/go-Q262

## References

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unpublished

**CL3-018 15mg, 3000:**

unpublished

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# 2 heart failure

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **ivabradine vs placebo** | | | |

continued...

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| SHIFT , 2010<br>[ISRCTN70429960]<br>n=3241/3264<br>follow-up: 23 months | ivabradine<br>versus<br>placebo | patients with NYHA class 2-4 heart failure, an LVEF <35% , a resting heart rate >70 bpm, and a heart-failure hospitalization within the previous year | Parallel groups<br>double-blind<br>37 countries |
| **ivabradine 15mg vs placebo** | | | |
| BEAUTIFUL , 2008<br>[NCT00143507]<br>n=5479/5438<br>follow-up: 19 months<br>(range 16-24) | ivabradine target dose of 75 mg twice a day<br>versus<br>placebo | patients with coronary artery disease and left-ventricular systolic dysfunction (LVEF <=40% ) | double blind<br>33 countries |

More details and results :

- HR-slowing agents for heart failure in all type of patients at http://www.trialresultscenter.org/go-Q456

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