

# Clinical trials of CRT

TrialResults-center [www.trialresultscenter.org](http://www.trialresultscenter.org)

## 1 heart failure

| Trial   | Treatments   | Patients  | Trials design and methods       |
|---|--|---|---------------------------------|
| <b>Combined CRT + ICD vs no CRT</b>   |  |   |                                 |
| <b>RethinQ , 2007</b><br>[NCT00132977]<br>n=85/85<br>follow-up: 6 months      | cardiac-resynchronization therapy<br>ICD+CRT<br>versus<br>no cardiac-resynchronization therapy | patients with standard indication for an implantable cardioverter-defibrillator, NYHA 3, EF<35% , QRS<130ms, and evidence of mechanical dyssynchrony  | Parallel groups<br>open<br>USA  |
| <b>CRT vs no CRT</b>  |  |   |                                 |
| <b>REVERSE , 2008</b><br>[NCT00271154].]<br>n=419/191<br>follow-up: 12 months | CRT<br>versus<br>"placebo"   | patients with NYHA functional class I or II heart failure with a QRS $\geq$ 120 ms and a LV ejection fraction $\leq$ 40%  | Parallel groups<br>double blind |
| <b>MUSTIC-SR , 2001</b><br>n=58/58<br>follow-up: 3 months                     | CRT Medtronic/ELA medical<br>versus<br>CRT off   | patients with severe heart failure (New York Heart Association class III) due to chronic left ventricular systolic dysfunction, with normal sinus rhythm and a duration of the QRS interval of more than 150 msec     | Cross over<br>Single blind      |
| <b>MIRACLE , 2002</b><br>n=228/225<br>follow-up: 6 months                     | CRT Medtronic<br>versus<br>CRT off   | patients with moderate-to-severe symptoms of heart failure associated with an ejection fraction of 35 percent or less and a QRS interval of 130 msec  | Parallel groups<br>Bouble blind |
| <b>PATH-CHF , 2002</b><br>n=NA<br>follow-up: 1 month                          | CRT<br>versus<br>no CRT  | patients with heart failure and ventricular conduction delay  | Parallel groups<br>open         |
| <b>MUSTIC AF , 2002</b><br>n=43/43<br>follow-up: 3 months                     | CRT Medtronic/ELA medical<br>versus<br>CRT off   | patients with NYHA class III left ventricular systolic dysfunction, chronic atrial fibrillation, slow ventricular rate necessitating permanent ventricular pacing, and a wide QRS complex (paced width $\geq$ 200 ms) | Cross over<br>Single blind      |
| <b>CARE-HF , 2005</b><br>n=409/404<br>follow-up: 29.4 months                  | CRT medtronic<br>versus<br>no CRT  | patients with NYHA class III or IV heart failure due to left ventricular systolic dysfunction and cardiac dyssynchrony  | parallel group<br>open          |

continued...

| <b>Trial</b>  | <b>Treatments</b>   | <b>Patients</b>   | <b>Trials design and methods</b>                    |
|---|---|---|---|
| <b>RD-CHF , 2003</b><br>n=NA<br>follow-up:                                    | CRT<br>versus<br>no CRT   | patients with advanced heart failure  | Parallel groups                                     |
| <b>COMPANION (CRT vs MT) , 2004</b><br>n=617/308<br>follow-up: 16 months      | CRT guidant<br>versus<br>no CRT, optimized medical therapy  | patients with advanced heart failure (NYHA III or IV) due to ischemic and non-ischemic cardiomyopathy with EF $\leq 35\%$ and QRS duration $>120$ ms                                  | Parallel groups<br>open                             |
| <b>Garrigue , 2002</b><br>n=NA<br>follow-up:                                  | CRT<br>versus<br>no CRT   | patients with chronic atrial fibrillation, severe heart failure and QRS prolongation of $>or = 140$ ms  | Parallel groups<br>single blind                     |
| <b>Combined CRT + ICD vs no CRT no ICD</b>                                    |   |   |   |
| <b>AMIOVIRT , 2003</b><br>n=51/52<br>follow-up: 24 months                     | ICD<br>versus<br>amiodarone as medical therapy  | patients with non ischemic cardiomyopathy with EF $\leq 0.35$ and Nonsustained ventricular tachycardia  | Parallel groups<br>open                             |
| <b>COMPANION (CRT+ICD vs MT) , 2004</b><br>n=595/308<br>follow-up: 16 months  | ICD+CRT<br>versus<br>no ICT no CRT, optimized medical therapy   | patients with advanced heart failure (NYHA III or IV) due to ischemic and non-ischemic cardiomyopathy with EF $\leq 0.35$ and QRS duration $>120$ ms                                  | Parallel groups<br>open                             |
| <b>Combined CRT + ICD vs CRT</b>  |   |   |   |
| <b>COMPANION (CRT+ICD vs CRT) , 2004</b><br>n=595/617<br>follow-up: 16 months | ICD+CRT<br>versus<br>CRT  | patients with advanced heart failure (NYHA III or IV) due to ischemic and non-ischemic cardiomyopathy with EF $\leq 0.35$ and QRS duration $>120$ ms                                  | Parallel groups<br>open                             |
| <b>Combined CRT + ICD vs ICD alone</b>  |   |   |   |
| <b>MIRACLE-ICD-II , 2004</b><br>n=85/101<br>follow-up: 6 months               | ICD+CRT (and optimalmedical treatment)<br>versus<br>ICD (optimalmedical treatment)  | NYHA class II heart failure patients on optimal medical therapy with a left ventricular (LV) ejection fraction $\leq 35\%$ , a QRS $\geq 130$ ms, and a class I indication for an ICD | Parallel groups<br>double blind                     |
| <b>MADIT CRT , 2009</b><br>[NCT00180271]<br>n=1089/731<br>follow-up: 2 years  | Cardiac resynchronization therapy with implantable cardioverter defibrillator<br>versus<br>implantable cardioverter defibrillator alone | patients with asymptomatic or mildly symptomatic heart failure (NYHA I/II), LEVF $\leq 30\%$ and QRS $\geq 130$ ms  | Parallel groups<br>blinded<br>United States, Europe |

continued...

| <b>Trial</b>  | <b>Treatments</b>  | <b>Patients</b>   | <b>Trials design and methods</b>                                     |
|---|--|---|--|
| <b>RAFT , 2010</b><br>[NCT00251251]<br>n=894/904<br>follow-up: 40 months                      | ICD plus CRT<br>versus<br>ICD alone  | patients with New York Heart Association (NYHA) class II or III heart failure, a left ventricular ejection fraction of 30% or less, and an intrinsic QRS duration of 120 msec or more or a paced QRS duration of 200 msec or more | Parallel groups<br>double-blind<br>Canada, Europe, Turkey, Australia |
| <b>MIRACLE-ICD-I , 2003</b><br>n=187/182<br>follow-up: 6 months                               | ICD+CRT (plus optimal medical treatment)<br>versus<br>ICD (plus optimal medical treatment)       | patients with NYHA class III or IV congestive HF despite appropriate medical management   | Parallel groups<br>double blind                                      |
| <b>CONTAK-CD , 2003</b><br>n=245/245<br>follow-up: 4.7 months                                 | ICD+CRT<br>versus<br>ICD (no CRT)  | patients with symptomatic heart failure, intraventricular conduction delay, and malignant ventricular tachyarrhythmias  | Parallel groups<br>open  |
| <b>CRT with triple site ventricular stimulation vs conventional cardiac resynchronization</b> |  |   |  |
| <b>NCT00887237</b> <i>ongoing</i><br>n=NA<br>follow-up:                                       | CRT with triple site ventricular stimulation<br>versus<br>Conventional cardiac resynchronization | patients with NYHA Class III/IV heart failure   | Parallel groups<br>open  |

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More details and results :

- resynchronization (CRT) - defibrillators (ICD) for heart failure in patients with non ischaemic cardiomyopathy at <http://www.trialresultscenter.org/go-Q15>
- resynchronization (CRT) - defibrillators (ICD) for heart failure in all type of patients at <http://www.trialresultscenter.org/go-Q104>
- resynchronization (CRT) - defibrillators (ICD) for heart failure in mildly symptomatic heart failure with prolonged QRS interval at <http://www.trialresultscenter.org/go-Q349>

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### **NCT00887237, :**

ongoing trial

## **2 prevention of sudden death**

| <b>Trial</b>                        | <b>Treatments</b> | <b>Patients</b> | <b>Trials design and methods</b> |
|-------------------------------------|-------------------|-----------------|----------------------------------|
| <b>Combined CRT + ICD vs no CRT</b> |                   |                 |                                  |

continued...

| <b>Trial</b>  | <b>Treatments</b>  | <b>Patients</b>  | <b>Trials design and methods</b> |
|---|--|--|----------------------------------|
| RethinQ , 2007<br>[NCT00132977]<br>n=85/85<br>follow-up: 6 months | cardiac-resynchronization therapy<br>ICD+CRT<br>versus<br>no cardiac-resynchronization therapy | patients with standard indication for an implantable cardioverter-defibrillator, NYHA 3, EF<35% , QRS<130ms, and evidence of mechanical dyssynchrony   | Parallel groups<br>open<br>USA   |
| <b>CRT vs no CRT</b>  |  |  |                                  |
| MUSTIC-SR , 2001<br>n=58/58<br>follow-up: 3 months                | CRT Medtronic/ELA medical<br>versus<br>CRT off   | patients with severe heart failure (New York Heart Association class III) due to chronic left ventricular systolic dysfunction, with normal sinus rhythm and a duration of the QRS interval of more than 150 msec  | Cross over<br>Single blind       |
| MIRACLE , 2002<br>n=228/225<br>follow-up: 6 months                | CRT Medtronic<br>versus<br>CRT off   | patients with moderate-to-severe symptoms of heart failure associated with an ejection fraction of 35 percent or less and a QRS interval of 130 msec   | Parallel groups<br>Bouble blind  |
| PATH-CHF , 2002<br>n=NA<br>follow-up: 1 month                     | CRT<br>versus<br>no CRT  | patients with heart failure and ventricular conduction delay   | Parallel groups<br>open          |
| MUSTIC AF , 2002<br>n=43/43<br>follow-up: 3 months                | CRT Medtronic/ELA medical<br>versus<br>CRT off   | patients with NYHA class III left ventricular systolic dysfunction, chronic atrial fibrillation, slow ventricular rate necessitating permanent ventricular pacing, and a wide QRS complex (paced width >or=200 ms) | Cross over<br>Single blind       |
| CARE-HF , 2005<br>n=409/404<br>follow-up: 29.4 months             | CRT medtronic<br>versus<br>no CRT  | patients with NYHA class III or IV heart failure due to left ventricular systolic dysfunction and cardiac dyssynchrony   | parallel group<br>open           |
| RD-CHF , 2003<br>n=NA<br>follow-up:                               | CRT<br>versus<br>no CRT  | patients with advanced heart failure   | Parallel groups                  |
| COMPANION (CRT vs MT) , 2004<br>n=617/308<br>follow-up: 16 months | CRT guidant<br>versus<br>no CRT, optimized medical therapy                                     | patients with advanced heart failure (NYHA III or IV) due to ischemic and non-ischemic cardiomyopathy with EF <=35% and QRS duration >120 ms   | Parallel groups<br>open          |
| Garrigue , 2002<br>n=NA<br>follow-up:                             | CRT<br>versus<br>no CRT  | patients with chronic atrial fibrillation, severe heart failure and QRS prolongation of >or = 140 ms   | Parallel groups<br>single blind  |
| <b>Combined CRT + ICD vs no CRT no ICD</b>                        |  |  |                                  |

continued...

| <b>Trial</b>  | <b>Treatments</b>   | <b>Patients</b>  | <b>Trials design and methods</b> |
|---|---|--|----------------------------------|
| <b>AMIOVIRT , 2003</b><br>n=51/52<br>follow-up: 24 months                                     | ICD<br>versus<br>amiodarone as medical therapy  | patients with non ischemic<br>cardiomyopathy with EF <=0.35 and<br>Nonsustained ventricular tachycardia  | Parallel groups<br>open          |
| <b>COMPANION (CRT+ICD<br/>vs MT) , 2004</b><br>n=595/308<br>follow-up: 16 months              | ICD+CRT<br>versus<br>no ICT no CRT, optimized medical<br>therapy                                    | patients with advanced heart failure<br>(NYHA III or IV) due to ischemic and<br>non-ischemic cardiomyopathy with EF<br><=0.35 and QRS duration >120 ms                                 | Parallel groups<br>open          |
| <b>Combined CRT + ICD vs CRT</b>  |   |  |                                  |
| <b>COMPANION (CRT+ICD<br/>vs CRT) , 2004</b><br>n=595/617<br>follow-up: 16 months             | ICD+CRT<br>versus<br>CRT  | patients with advanced heart failure<br>(NYHA III or IV) due to ischemic and<br>non-ischemic cardiomyopathy with EF<br><=0.35 and QRS duration >120 ms                                 | Parallel groups<br>open          |
| <b>Combined CRT + ICD vs ICD alone</b>  |   |  |                                  |
| <b>MIRACLE-ICD-II , 2004</b><br>n=85/101<br>follow-up: 6 months                               | ICD+CRT (and optimalmedical<br>treatment)<br>versus<br>ICD (optimalmedical treatment)               | NYHA class II heart failure patients on<br>optimal medical therapy with a left<br>ventricular (LV) ejection fraction <=35%<br>, a QRS >=130 ms, and a class I<br>indication for an ICD | Parallel groups<br>double blind  |
| <b>MIRACLE-ICD-I , 2003</b><br>n=187/182<br>follow-up: 6 months                               | ICD+CRT (plus optimal medical<br>treatment)<br>versus<br>ICD (plus optimal medical treatment)       | patients with NYHA class III or IV<br>congestive HF despite appropriate<br>medical management  | Parallel groups<br>double blind  |
| <b>CONTAK-CD , 2003</b><br>n=245/245<br>follow-up: 4.7 months                                 | ICD+CRT<br>versus<br>ICD (no CRT)   | patients with symptomatic heart failure,<br>intraventricular conduction delay, and<br>malignant ventricular tachyarrhythmias   | Parallel groups<br>open          |
| <b>CRT with triple site ventricular stimulation vs conventional cardiac resynchronization</b> |   |  |                                  |
| <b>NCT00887237 ongoing</b><br>n=NA<br>follow-up:  | CRT with triple site ventricular<br>stimulation<br>versus<br>Conventional cardiac resynchronization | patients with NYHA Class III/IV hert<br>failure  | Parallel groups<br>open          |

More details and results :

- resynchronization (CRT) - defibrillators (ICD) for prevention of sudden death in primary prevention at <http://www.trialresultscenter.org/go-Q107>
- resynchronization (CRT) - defibrillators (ICD) for prevention of sudden death in heart failure at <http://www.trialresultscenter.org/go-Q109>

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ongoing trial