

# Clinical trials of off-pump CABG for CABG surgery in all type of patients

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## 1 CABG

| Trial  | Treatments  | Patients   | Trials design and methods                             |
|--|---|--|---|
| <b>off-pump vs on-pump</b>   |   |  |   |
| <b>Al-Ruzzeh b , 2006</b><br>n=84/84<br>follow-up: 6 months                    | off-pump<br>versus<br>coronary artery bypass grafting surgery using<br>cardiopulmonary bypass                     | patients requiring primary isolated coronary<br>artery bypass grafting surgery   | Parallel groups<br>open with blinded assessment<br>UK |
| <b>Alwan , 2004</b><br>n=35/35<br>follow-up: In-hospital/30-day<br>mortality   | beating heart revascularization<br>versus<br>arrested heart revascularization                                     | patients undergoing CABG   | Parallel groups<br>open                               |
| <b>Ascione , 2006</b><br>n=20/20<br>follow-up: In-hospital                     | off-pump coronary artery bypass grafting<br>versus<br>artery bypass grafting with cardiopulmonary<br>bypass       | patient undergoing CABG  | Parallel groups<br>open                               |
| <b>Ascionee , 2005</b><br>n=10/10<br>follow-up: In-hospital                    | off-pump CABG<br>versus<br>on-pump CABG   | patient undergoing CABG  | Parallel groups<br>open                               |
| <b>Baker , 2001</b><br>n=12/14<br>follow-up:                                   | off pump surgery using the Octopus II<br>stabilizing system<br>versus<br>conventional CABG cardiopulmonary bypass | elective patients requiring surgery for double<br>or triple vessel disease   | open  |
| <b>BBS (Moller) , 2010</b><br>[NCT00120991]<br>n=177/164<br>follow-up: 30 days | off-pump CABG<br>versus<br>on-pump CABG   | patients >54 years of age with three-vessel<br>coronary artery disease with EuroSCORE of<br>5-16 undergoing elective or sub-acute<br>coronary artery bypass grafting | Parallel groups<br>open blind assessor                |
| <b>BHACAS I (Ascione) , 1999</b><br>n=100/100<br>follow-up: 65279;25 months    | off-pump<br>versus<br>on-pump   | cardiac surgery candidates   | Parallel groups<br>open with blinded assessment       |
| <b>BHACAS II (Angelini) , 2002</b><br>n=100/101<br>follow-up: 13.7 months      | off-pump<br>versus<br>on-pump   | patients with myocardial infarction in the<br>past month or who required grafting of the<br>circumflex artery distal to the first obtuse<br>marginal branch          | Parallel groups<br>open with blinded assessment       |
| <b>Caputo , 2002</b><br>n=20/20<br>follow-up: In-hospital                      | beating heart surgery (off-pump)<br>versus<br>conventional CABG with cardiopulmonary<br>bypass                    | patients undergoing coronary artery bypass<br>grafting   | Parallel groups<br>open                               |

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| <b>Trial</b>  | <b>Treatments</b>  | <b>Patients</b>   | <b>Trials design and methods</b> |
|---|--|---|----------------------------------|
| <b>Carrier , 2003</b><br>n=32/33<br>follow-up: In-hospital/30-day mortality | off-pump CABG<br>versus<br>on-pump CABG  | high-risk patients  | Parallel groups<br>open          |
| <b>Covino , 2001</b><br>n=21/16<br>follow-up: In-hospital                   | -  | -   | open                             |
| <b>Czerny , 2000</b><br>n=NA  | -  | -   | open                             |
| <b>Czerny b , 2001</b><br>n=NA  | -  | -   | open                             |
| <b>Diegeler , 2000</b><br>n=20/20<br>follow-up: In-hospital                 | coronary artery bypass operation without cardiopulmonary bypass (off-pump CABG)<br>versus<br>conventional coronary artery bypass operation using cardiopulmonary bypass                            | cardiac surgery candidates  | Parallel groups<br>open          |
| <b>DOORS , 2009</b><br>[NCT00123981]<br>n=NA<br>follow-up: 30 days          | Off-Pump Coronary Artery Bypass Grafting<br>versus<br>on-pump CABG   | elderly patients  | Parallel groups<br>open          |
| <b>Dorman , 2004</b><br>n=NA  | -  | -   | open                             |
| <b>Gasz , 2004</b><br>n=NA  | -  | -   | open                             |
| <b>Gerola , 2001</b><br>n=80/80<br>follow-up: In-hospital/30-day mortality  | off-pump coronary artery bypass<br>versus<br>on-pump CABG  | low-risk patients undergoing CABG   | Parallel groups<br>open          |
| <b>Gu , 1998</b><br>n=31/31<br>follow-up: 65279;In-hospital                 | minimally invasive coronary artery bypass grafting<br>versus<br>conventional coronary artery bypass grafting with cardiopulmonary bypass   | patients with isolated stenosis of the left anterior descending coronary artery | Parallel groups<br>open          |
| <b>Guler , 2001</b><br>n=NA   | -  | -   | open                             |
| <b>Gulielmos , 1999</b><br>n=20/20<br>follow-up: 3 months                   | off-pump coronary artery bypass with median sternotomy or off-pump procedure and lateral minithoracotomy<br>versus<br>conventional technique or lateral minithoracotomy and cardiopulmonary bypass | patients with coronary artery single-vessel disease                             | Parallel groups<br>open          |
| <b>Jares , 2006</b><br>n=10/10<br>follow-up: 24 h                           | off-pump CABG<br>versus<br>on-pump CABG  | patients scheduled for coronary bypass grafting                                 | Parallel groups<br>open          |

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| <b>Trial</b>   | <b>Treatments</b>   | <b>Patients</b>  | <b>Trials design and methods</b>                                   |
|--|---|--|--|
| <b>Khan , 2004</b><br>n=54/49<br>follow-up: 3 months                       | off-pump CABG<br>versus<br>conventional "on-pump" surgery   | patient undergoing CABG  | Parallel groups<br>open  |
| <b>Kobayashi , 2005</b><br>n=81/86<br>follow-up: 30 days                   | off-pump CABG<br>versus<br>on-pump CABG   | patients referred for elective primary CABG                              | Parallel groups<br>open  |
| <b>Kunes , 2007</b><br>n=17/17<br>follow-up: 7 days                        | off-pump CABG<br>versus<br>on-pump CABG   | patient undergoing CABG  | Parallel groups<br>open  |
| <b>Lee , 2003</b><br>n=30/30<br>follow-up:                                 | off-pump CABG<br>versus<br>conventional on-pump CABG  | patients undergoing CABG   | open   |
| <b>Legare , 2004</b><br>[NCT00216957]<br>n=150/150<br>follow-up: 3.8 years | off-pump CABG<br>versus<br>on-pump CABG   | patients undergoing CABG   | Parallel groups<br>open  |
| <b>Lingaas , 2003</b><br>n=60/60<br>follow-up: 12 months                   | off-pump CABG<br>versus<br>on-pump CABG   | patient undergoing CABG  | Parallel groups<br>open  |
| <b>Matata , 2000</b><br>n=10/10<br>follow-up: In-hospital                  | off-pump<br>versus<br>on-pump   | cardiac surgery candidates   | Parallel groups<br>open  |
| <b>Michaux , 2006</b><br>n=25/25<br>follow-up: 30 days                     | off-pump CABG<br>versus<br>on-pump CABG   | patients scheduled for elective coronary<br>artery bypass surgery        | Parallel groups<br>open  |
| <b>Motallebzadeh , 2004</b><br>n=15/20<br>follow-up: In-hospital           | off-pump CABG<br>versus<br>on-pump CABG   | patients admitted for CABG   | Parallel groups<br>open  |
| <b>Motallebzadeh b , 2006</b><br>n=108/104<br>follow-up: 6 months          | off-pump CABG<br>versus<br>on-pump CABG   | patients admitted for elective coronary artery<br>bypass graft surgery   | Parallel groups<br>open  |
| <b>Muneretto , 2003</b><br>n=NA  | -   | -  | open   |
| <b>Niranjan , 2006</b><br>n=40/40<br>follow-up: In-hospital                | off-pump CABG with or without cell saver<br>blood transfusion<br>versus<br>on-pump CABG with or without cell saver<br>blood transfusion | patient undergoing CABG  | open   |
| <b>OCTOPUS (van Dijk) , 2002</b><br>n=142/139<br>follow-up: 5 years        | off-pump surgery<br>versus<br>on-pump surgery   | patients with predominantly single- or<br>double-vessel coronary disease | Parallel groups<br>open with blinded assessment<br>the Netherlands |
| <b>Ozkara , 2007</b><br>n=22/22<br>follow-up: In-hospital                  | off-pump CABG<br>versus<br>on-pump CABG   | patients admitted for elective CABG                                      | Parallel groups<br>open  |

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| <b>Trial</b>   | <b>Treatments</b>   | <b>Patients</b>  | <b>Trials design and methods</b>                      |
|--|---|--|---|
| Paparella , 2006<br>n=15/16<br>follow-up: In-hospital                          | off-pump CABG<br>versus<br>on-pump CABG                                       | patient undergoing CABG  | Parallel groups<br>open                               |
| Parolari , 2003<br>n=NA  | -   | -  | open  |
| Parolari b , 2003<br>n=NA  | -   | -  | open  |
| Penttila , 2001<br>n=11/11<br>follow-up: In-hospital                           | off-pump CABG<br>versus<br>on-pump CABG                                       | patients requiring CABG  | Parallel groups<br>open                               |
| PRAGUE 4 (Widimsky) ,<br>2004<br>n=208/192<br>follow-up: 1 y                   | off pump<br>versus<br>on pump   | cardiac surgery candidates   | Parallel groups<br>open                               |
| PROMISS (Uva) , 2010<br>n=75/75<br>follow-up: 5 weeks (498 days)               | off-pump<br>versus<br>on-pump   | patients between 30 and 90 years of age with<br>multi-vessel coronary artery disease<br>undergoing CABG with at least three distal<br>coronary anastomoses | Parallel groups<br>open                               |
| Puskas , 2004<br>n=NA  | -   | -  | open  |
| Raja b , 2003<br>n=150/150<br>follow-up: In-hospital                           | on-pump CABG<br>versus<br>off-pump CABG                                       | patients undergoing CABG   | Parallel groups<br>open                               |
| ROOBY (Shroyer) , 2009<br>[NCT00032630]<br>n=1104/1099<br>follow-up: 1 mo (1y) | off-pump CABG<br>versus<br>on-pump CABG                                       | patients scheduled for urgent or elective<br>coronary bypass surgery   | Parallel groups<br>open<br>USA                        |
| Sahlman , 2003<br>n=NA   | -   | -  | open  |
| Selvanayagam , 2004<br>n=30/30<br>follow-up: In-hospital                       | off-pump CABG<br>versus<br>on-pump CABG                                       | patients undergoing multivessel CABG   | Parallel groups<br>open                               |
| SMART (Staton) , 2003<br>n=100/100<br>follow-up: 12 months                     | off-pump coronary artery bypass<br>versus<br>CABG with cardiopulmonary bypass | patients unselected for coronary anatomy,<br>ventricular function, or comorbidities  | Parallel groups<br>open with blinded assessment<br>US |
| Syed , 2004<br>n=NA  | -   | -  | open  |
| Tang , 2002<br>n=NA  | -   | -  | open  |
| Tatoulis , 2006<br>n=50/50<br>follow-up: 30 days                               | off-pump CABG<br>versus<br>on-pump CABG                                       | candidates for elective CABG   | Parallel groups<br>open                               |

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| Trial  | Treatments                              | Patients  | Trials design and methods       |
|--|---|---|---------------------------------|
| Vedin , 2006<br>n=NA<br>follow-up:                                     | off-pump CABG<br>versus<br>on-pump CABG | patients between 50 and 80 years with stable angina pectoris, ejection fraction >30% , serum creatinine <150 micromol/l, and lack of tight main stem stenosis | open                            |
| Velisaris , 2003<br>n=NA   | -                                       | -   | open                            |
| Vural , 1995<br>n=NA   | -                                       | -   | open                            |
| Wan , 2004<br>n=NA   | -                                       | -   | open                            |
| Wandschneider , 2000<br>n=NA   | -                                       | -   | open                            |
| Zamvar , 2002<br>n=30/30<br>follow-up: 10 weeks                        | off-pump CABG<br>versus<br>on-pump CABG | patients undergoing coronary artery bypass graft surgery for triple vessel disease  | Parallel groups<br>open<br>UK   |
| GOPCABE <i>ongoing</i><br>[NCT00719667]<br>n=NA<br>follow-up:          | Off-pump CABG<br>versus<br>ON-pump CABG | Elderly   | Parallel groups<br>open         |
| OCTOPUS II <i>ongoing</i><br>n=NA                                      | -                                       | -   |                                 |
| Ontario <i>ongoing</i><br>[NCT00259493]<br>n=NA<br>follow-up: 3 months | Off-Pump CABG<br>versus<br>On-Pump CABG | -   | Parallel groups<br>double blind |

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