

# Clinical trials of FFR-guided PCI

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

## 1 stable angina

Trial	Treatments	Patients	Trials design and methods
<b>FFR-guided PCI vs no PCI</b>			
<b>FAME II , 2012</b> [NCT01132495] n=447/441 follow-up:	fractional-flow-reserve (FFR)-guided stenting versus optimal medical therapy alone	patients patients with stable CAD found on FFR to have hemodynamically relevant disease	Parallel groups Europe, US, and Canada
<b>FAME , 2008</b> [NCT00267774] n=509/496 follow-up: 1 year	FFR-guided PCI (PCI with implantation of drug-eluting stents guided by FFR measurements in addition to angiography versus angiography-PCI (PCI with implantation of drug-eluting stents guided by angiography alone)	patients with multivessel coronary artery disease	Parallel groups open USA, Europe
<b>DEFER , 2001</b> n=90/91 follow-up: 24 months	PCI versus deferral (no PCI)	patients for whom PTCA was planned and who did not have documented ischemia and with fractional flow reserve >0.75	Parallel groups open

More details and results :

- myocardial revascularization for stable angina in all type of patient at <http://www.trialresultscenter.org/go-Q25>

## References

### FAME II, 2012:

De Bruyne B, Pijls NH, Kalesan B, Barbato E, Tonino PA, Piroth Z, Jagic N, Mobius-Winckler S, Rioufol G, Witt N, Kala P, Maccarthy P, Engstrm T, Oldroyd KG, Mavromatis K, Manoharan G, Verlee P, Frobert O, Curzen N, Johnson JB, Jni P, Fearon WF Fractional Flow Reserve-Guided PCI versus Medical Therapy in Stable Coronary Disease. N Engl J Med 2012 Aug 27;: [22924638] [10.1056/NEJMoa1205361](https://doi.org/10.1056/NEJMoa1205361)

De Bruyne B, Fearon WF, Pijls NH, Barbato E, Tonino P, Piroth Z, Jagic N, Mobius-Winckler S, Riouffol G, Witt N, Kala P, MacCarthy P, Engstrm T, Oldroyd K, Mavromatis K, Manoharan G, Verlee P, Frobert O, Curzen N, Johnson JB, Limacher A, Nesch E, Jni P Fractional Flow Reserve-Guided PCI for Stable Coronary Artery Disease. N Engl J Med 2014 Sep 1;: [25176289] [10.1056/NEJMoa1408758](https://doi.org/10.1056/NEJMoa1408758)

### FAME, 2008:

Pijls NH, Fearon WF, Tonino PA, Siebert U, Ikeno F, Bornschein B, van't Veer M, Klauss V, Manoharan G, Engstrm T, Oldroyd KG, Ver Lee PN, MacCarthy PA, De Bruyne B Fractional flow reserve versus angiography for guiding percutaneous coronary intervention in patients with multivessel coronary artery disease: 2-year follow-up of the FAME (Fractional Flow Reserve Versus Angiography for Multivessel Evaluation) study. J Am Coll Cardiol 2010;56:177-84 [20537493] [10.1016/j.jacc.2010.04.012](https://doi.org/10.1016/j.jacc.2010.04.012)

Tonino PA, De Bruyne B, Pijls NH, Siebert U, Ikeno F, van' t Veer M, Klauss V, Manoharan G, Engstrm T, Oldroyd KG, Ver Lee PN, MacCarthy PA, Fearon WF Fractional flow reserve versus angiography for guiding percutaneous coronary intervention. N Engl J Med 2009;360:213-24 [19144937]

Pijls NH, Fearon WF, Tonino PA, Siebert U, Ikeno F, Bornschein B, van't Veer M, Klauss V, Manoharan G, Engstrm T, Oldroyd KG, Ver Lee PN, MacCarthy PA, De Bruyne B Fractional flow reserve versus angiography for guiding percutaneous coronary intervention in patients with multivessel coronary artery disease: 2-year follow-up of the FAME (Fractional Flow Reserve Versus Angiography for Multivessel Evaluation) study. J Am Coll Cardiol 2010;56:177-84 [20537493]

Sels JW, Tonino PA, Siebert U, Fearon WF, Van't Veer M, De Bruyne B, Pijls NH Fractional flow reserve in unstable angina and non-ST-segment elevation myocardial infarction experience from the FAME (Fractional flow reserve versus Angiography for Multivessel Evaluation) study. JACC Cardiovasc Interv 2011;4:1183-9 [22115657]

#### DEFER, 2001:

Bech GJ, De Bruyne B, Pijls NH, de Muinck ED, Hoorntje JC, Escaned J, Stella PR, Boersma E, Bartunek J, Koolen JJ, Wijns W Fractional flow reserve to determine the appropriateness of angioplasty in moderate coronary stenosis: a randomized trial. Circulation 2001;103:2928-34 [11413082]

## 2 coronary artery disease

2

Trial	Treatments	Patients	Trials design and methods
<b>FFR-guided PCI vs no PCI</b>			
<b>FAME II , 2012</b> [NCT01132495] n=447/441 follow-up:	fractional-flow-reserve (FFR)-guided stenting versus optimal medical therapy alone	patients patients with stable CAD found on FFR to have hemodynamically relevant disease	Parallel groups Europe, US, and Canada
<b>FAME , 2008</b> [NCT00267774] n=509/496 follow-up: 1 year	FFR-guided PCI (PCI with implantation of drug-eluting stents guided by FFR measurements in addition to angiography versus angiography-PCI (PCI with implantation of drug-eluting stents guided by angiography alone)	patients with multivessel coronary artery disease	Parallel groups open USA, Europe
<b>DEFER , 2001</b> n=90/91 follow-up: 24 months	PCI versus deferral (no PCI)	patients for whom PTCA was planned and who did not have documented ischemia and with fractional flow reserve >0.75	Parallel groups open

More details and results :

- myocardial revascularization for coronary artery disease in all type of patient at <http://www.trialresultscenter.org/go-Q26>
- fractional-flow-reserve-guided PCI for coronary artery disease in all type of patients at <http://www.trialresultscenter.org/go-Q563>

## References

### **FAME II, 2012:**

De Bruyne B, Pijls NH, Kalesan B, Barbato E, Tonino PA, Piroth Z, Jagic N, Mobius-Winckler S, Rioufol G, Witt N, Kala P, Maccarthy P, Engstrm T, Oldroyd KG, Mavromatis K, Manoharan G, Verlee P, Frobert O, Curzen N, Johnson JB, Jni P, Fearon WF Fractional Flow Reserve-Guided PCI versus Medical Therapy in Stable Coronary Disease. *N Engl J Med* 2012 Aug 27;: [22924638] [10.1056/NEJMoa1205361](https://doi.org/10.1056/NEJMoa1205361)

De Bruyne B, Fearon WF, Pijls NH, Barbato E, Tonino P, Piroth Z, Jagic N, Mobius-Winckler S, Riouffol G, Witt N, Kala P, MacCarthy P, Engstrm T, Oldroyd K, Mavromatis K, Manoharan G, Verlee P, Frobert O, Curzen N, Johnson JB, Limacher A, Nesch E, Jni P Fractional Flow Reserve-Guided PCI for Stable Coronary Artery Disease. *N Engl J Med* 2014 Sep 1;: [25176289] [10.1056/NEJMoa1408758](https://doi.org/10.1056/NEJMoa1408758)

### **FAME, 2008:**

Pijls NH, Fearon WF, Tonino PA, Siebert U, Ikeno F, Bornschein B, van't Veer M, Klauss V, Manoharan G, Engstrm T, Oldroyd KG, Ver Lee PN, MacCarthy PA, De Bruyne B Fractional flow reserve versus angiography for guiding percutaneous coronary intervention in patients with multivessel coronary artery disease: 2-year follow-up of the FAME (Fractional Flow Reserve Versus Angiography for Multivessel Evaluation) study. *J Am Coll Cardiol* 2010;56:177-84 [20537493] [10.1016/j.jacc.2010.04.012](https://doi.org/10.1016/j.jacc.2010.04.012)

Tonino PA, De Bruyne B, Pijls NH, Siebert U, Ikeno F, van' t Veer M, Klauss V, Manoharan G, Engstrm T, Oldroyd KG, Ver Lee PN, MacCarthy PA, Fearon WF Fractional flow reserve versus angiography for guiding percutaneous coronary intervention. *N Engl J Med* 2009;360:213-24 [19144937]

Pijls NH, Fearon WF, Tonino PA, Siebert U, Ikeno F, Bornschein B, van't Veer M, Klauss V, Manoharan G, Engstrm T, Oldroyd KG, Ver Lee PN, MacCarthy PA, De Bruyne B Fractional flow reserve versus angiography for guiding percutaneous coronary intervention in patients with multivessel coronary artery disease: 2-year follow-up of the FAME (Fractional Flow Reserve Versus Angiography for Multivessel Evaluation) study. *J Am Coll Cardiol* 2010;56:177-84 [20537493]

Sels JW, Tonino PA, Siebert U, Fearon WF, Van't Veer M, De Bruyne B, Pijls NH Fractional flow reserve in unstable angina and non-ST-segment elevation myocardial infarction experience from the FAME (Fractional flow reserve versus Angiography for Multivessel Evaluation) study. *JACC Cardiovasc Interv* 2011;4:1183-9 [22115657]

### **DEFER, 2001:**

Bech GJ, De Bruyne B, Pijls NH, de Muinck ED, Hoorntje JC, Escaned J, Stella PR, Boersma E, Bartunek J, Koolen JJ, Wijns W Fractional flow reserve to determine the appropriateness of angioplasty in moderate coronary stenosis: a randomized trial. *Circulation* 2001;103:2928-34 [11413082]

Entry terms: PCI