

**Fractional Flow Reserve-Guided Percutaneous Coronary
Intervention plus Optimal Medical Treatment versus
Optimal Medical Treatment Alone in Patients with Stable
Coronary Artery Disease
(FAME II Trial)**

Preliminary Results

Clinicaltrials.gov NCT01132495

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for the FAME II study group**



Potential conflicts of interest

Speaker's name: Bernard De Bruyne

☒ **I have the following** potential conflicts of interest to report:

- ☒ Research contracts
- ☒ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

☐ I do not have any potential conflict of interest

Study Supported by St Jude Medical

Background

- In patients with clinically stable coronary disease, PCI has not been shown to affect clinical outcomes such as death, non-fatal myocardial infarction, and the need for urgent revascularisation
- In previous trials on revascularisation, the latter has been guided by the angiographic appearance of the lesions
- It is likely that in previous trials dealing with patients with non-acute CAD, a sizable proportion of patients without ischaemia has been included

Objective

To compare the clinical outcomes, of FFR-guided contemporary PCI plus optimal medical treatment (OMT) versus OMT alone in patients with stable coronary disease, with invasively established ischemia-inducing stenoses in large coronary arteries

Flow Chart

Stable patients scheduled for 1, 2 or 3 vessel DES stenting

FFR in all target lesions

Randomised Trial

Registry

At least 1 stenosis
with $\text{FFR} \leq 0.80$

Randomisation 1:1

PCI + OMT

OMT

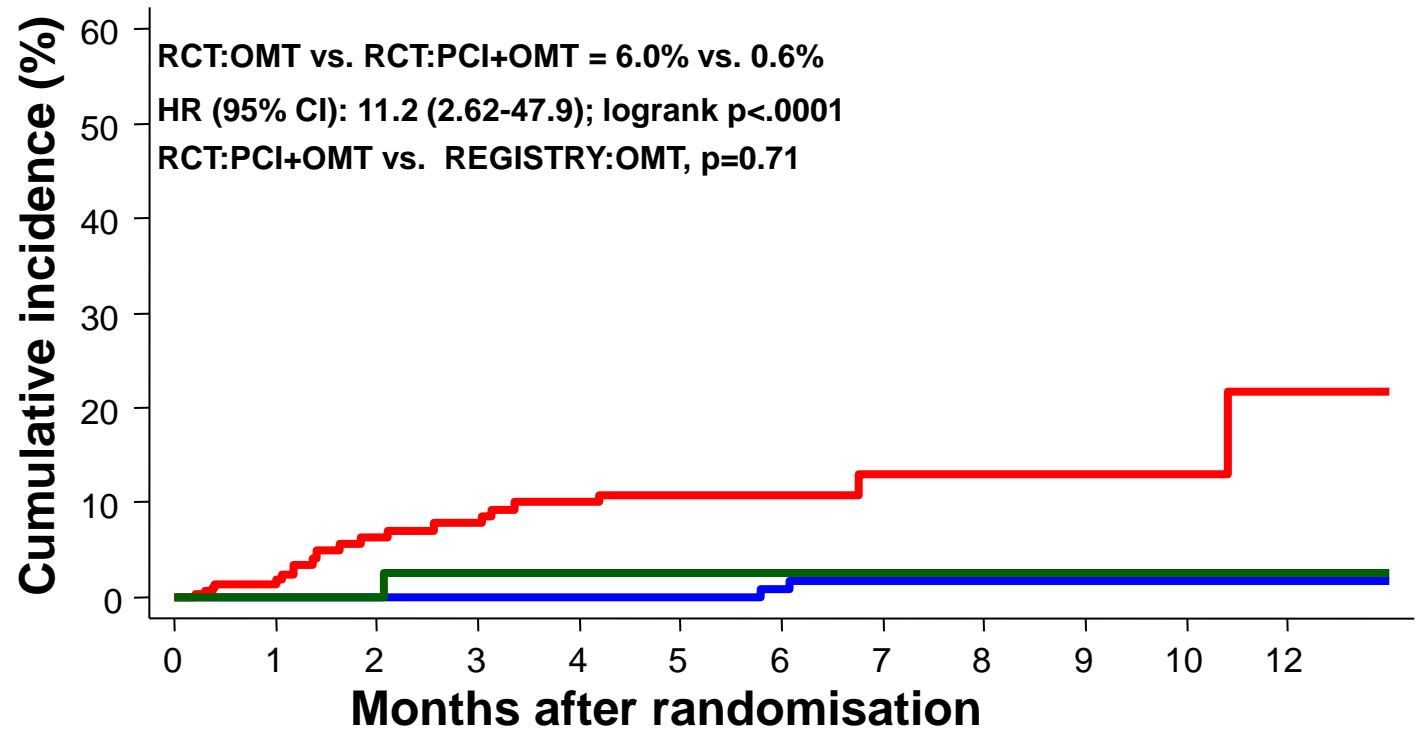
When all $\text{FFR} > 0.80$

OMT

50% randomly
assigned to FU

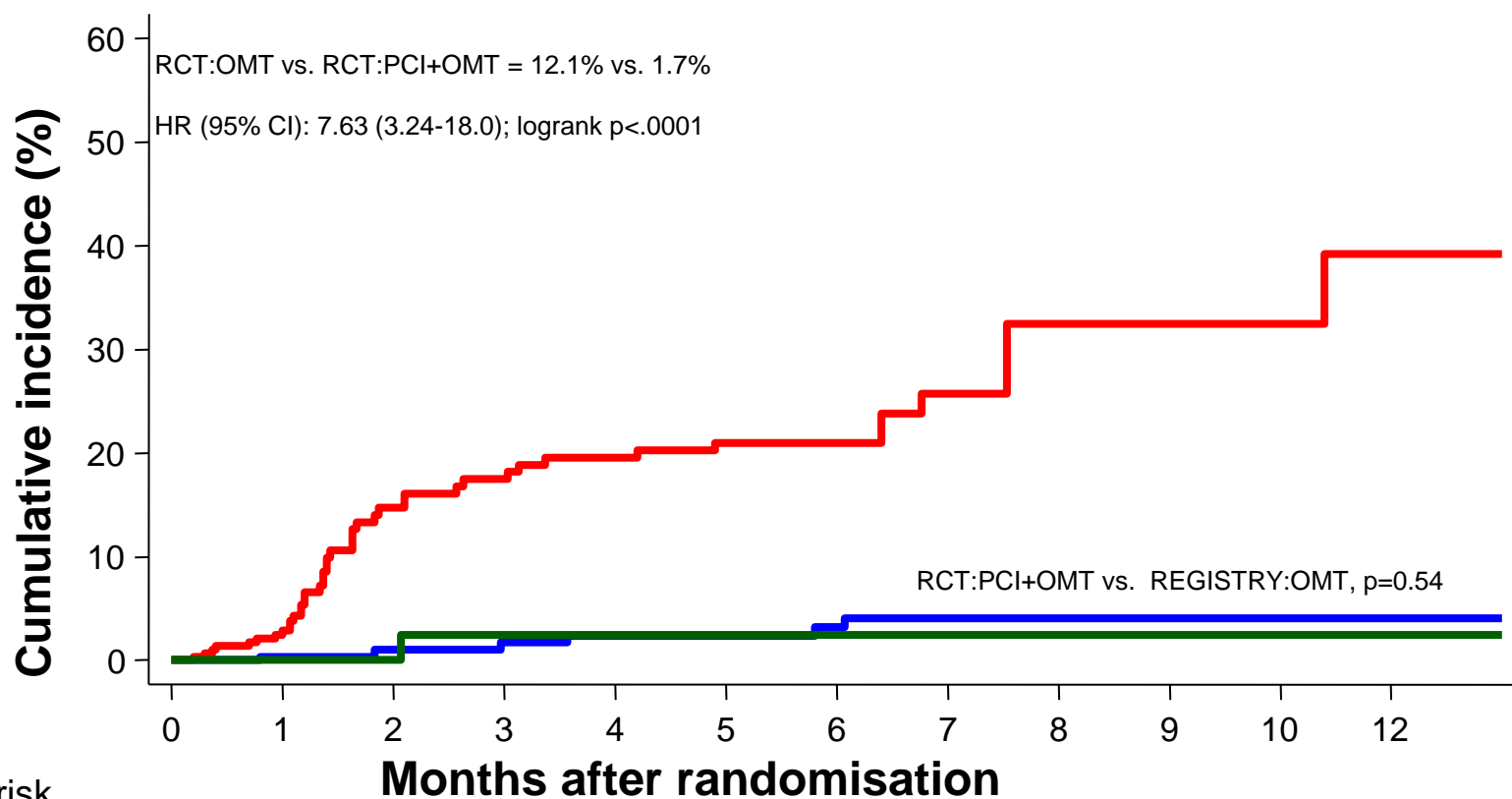
Follow-up after 1, 6 months, 1, 2, 3, 4, and 5 years

Rate of Urgent Revascularisation



No. at risk												
RCT:OMT only	339	235	127	125	121	119	85	19	10	10	10	8
RCT:PCI+OMT	352	257	146	144	144	143	116	25	18	18	18	18
REGISTRY:OMT only	131	88	41	40	40	40	35	4	1	1	1	1

Rate of Any Revascularisation



No. at risk												
RCT:OMT only	339	238	123	119	115	112	83	20	10	10	10	8
RCT:PCI+OMT	352	256	144	141	140	139	114	25	18	18	18	18
REGISTRY:OMT only	131	88	41	40	40	40	35	4	1	1	1	1

Conclusive remarks **for this preliminary dataset of the FAME II trial**

- In patients with stable CAD and at least one hemodynamically significant stenosis ($\text{FFR} \leq 0.80$) in at least one major epicardial artery, OMT alone was associated with a significantly larger number of urgent revascularizations than FFR-guided PCI plus OMT
- In patients with stable CAD without invasively documented ischaemia-inducing lesions ($\text{FFR} > 0.80$) OMT alone was associated with a very favourable clinical outcome