

# The **RIPC**ORD Study

ClinicalTrial.gov Identifier: NCT01070771

Does **R**outine **P**ressure wire assessment influence management strategy at **C**ORonary angiography for **D**iagnosis of chest pain?

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## Conflicts of Interests Declaration

This trial was funded by an unrestricted research grant from St Jude Medical Ltd. The company has played no role in trial design, prosecution, data collection & analysis

N Curzen has received speaker & consultancy fees from St Jude Medical Ltd but have received no personal financial reimbursement in relation to the RIPCORD trial

N Curzen has agreed an unrestricted educational grant with Volcano for 2013

Site	PI	Number
Southampton	N Curzen	55
Newcastle	A Zaman	35
Glasgow	K Oldroyd	35
Belfast	C Hanratty	20
Oxford	A Banning	16
Leeds	S Wheatcroft	16
Portsmouth	A Hobson	10
Derby	K Chitkara	7
Brighton	D Hildick-Smith	4
Taunton	D McKenzie	2

## Background

- Angiographic assessment of the functional significance of coronary artery disease (CAD) is flawed
- Ischaemia is the most important determinant of clinical outcome in CAD
- FFR is an accurate & reproducible method for detection of ischaemia
- DEFER, FAME & FAME 2 demonstrate better clinical outcome for FFR-guided treatment compared to angiography alone
- Despite this most patients with chest pain are assessed by angiogram alone

## Hypothesis

In patients being investigated for stable cardiac-sounding chest pain routine assessment of FFR in all the main coronary branches will significantly modify the management strategy derived from diagnostic angiography alone

Prospective, multicentre trial with paired samples as internal controls

Primary Outcome:

Number of cases in which management plan changes between angiogram and FFR data

Secondary Outcomes:

- a) Number of vessels with discrepant significance according to angiogram vs. FFR
- b) Distribution of 0,1,2,3 vessel disease by angiogram vs. FFR
- c) Requirement for revascularisation for left anterior descending, circumflex, right coronary according to angiogram vs. FFR

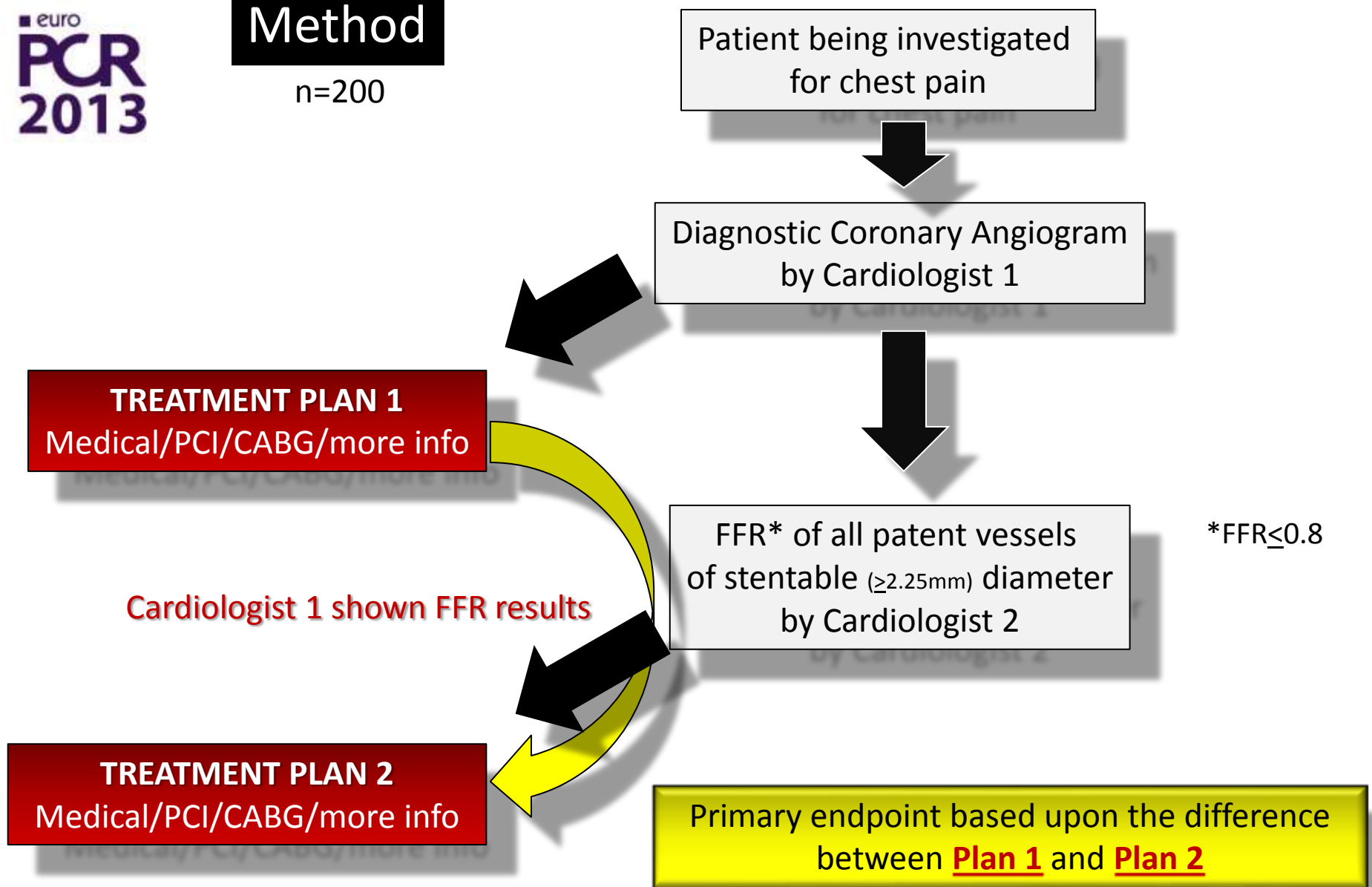
## Power Calculation

If we assume that 20% of patients will have their treatment decision altered as a result of the pressure wire analysis, with 50 patients in the study the 95% confidence interval for p is therefore  $20\% \pm 11\%$  i.e. 9% to 31%. These confidence intervals are wider than is clinically useful.

For the purposes of this study, therefore, appropriately narrow confidence intervals are gained with a sample size of 200, which offers 95% confidence intervals of 15% to 25%.

# Method

n=200



# Results: PRIMARY ENDPOINT

## Management of population by angiogram versus FFR

				FFR		PLAN 2		Total
		Medical	PCI	CABG	Further Info			
PLAN 1	Medical	63	6	3	0	72		
ANGIO	PCI	24	64	2	0	90		
	CABG	1	3	19	0	23		
	Further info	1	7	6	1	15		
Total		89	80	30	1	200		

Fishers exact test  $p < 0.0001$

### Summary

- Agreement about category of management in 147 out of 200 (74%)
  - ie after FFR management change in 26% of cases

## Results: SECONDARY ENDPOINT

Number of vessels labelled as significant by angiogram & Agreement in each category after FFR

		FFR					
		0	1	2	3	LM	Total
<b>ANGIO</b>	0	63	9	7	1	1	81
	1	24	54	5	0	1	84
	2	1	8	11	2	0	22
	3	1	1	2	6	1	11
	LM	0	0	0	0	2	2
Total		89	72	25	9	5	200

### Summary

In a total of 64 cases (32%), FFR leads to a change in the judgement as to whether a coronary artery has a “significant” lesion compared to angiogram alone



- Routine use of FFR at diagnostic coronary angiography results in a significant change in management of patients in 26% (Primary endpoint)
- In a total of 64 cases (32%), FFR leads to a change in the judgement as to whether a coronary artery has a “significant” lesion compared to angiogram alone (Secondary endpoint)
- These results have potentially important implications for clinical practice:
  - management of patients with stable angina by angiogram alone is flawed
  - management of patients would be improved by routine use of FFR at the diagnostic stage
- A large scale randomised trial of angiographic- versus FFR-guided assessment & management of patients undergoing diagnostic angiography with stable angina is now warranted

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## Acknowledgements

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Dr Omar Rana *Data cleaning & analysis*

Dr Borislav Dimitrov *Medical Statistician*

Dr Simon Corbett *Local Investigator*

Dr Alison Calver *Local Investigator*

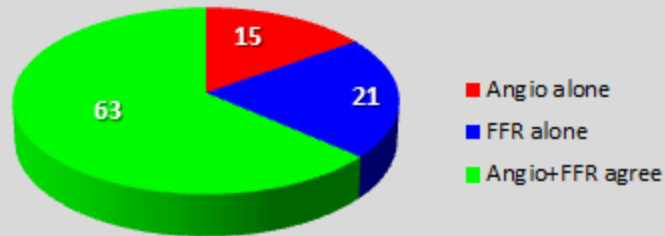
Dr Peter Golledge *Local Investigator*

Cath Lab staff in Southampton

## RIPCORDER Investigators & Coordinators

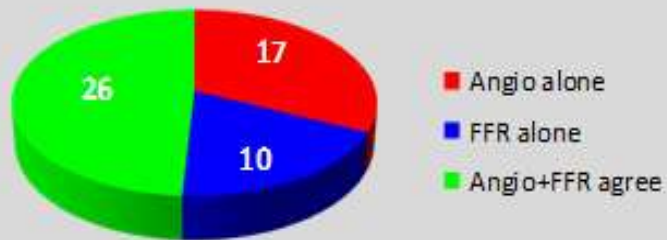
## Results: Indication for revascularisation of individual coronaries by angiogram & FFR

### Left Anterior Descending



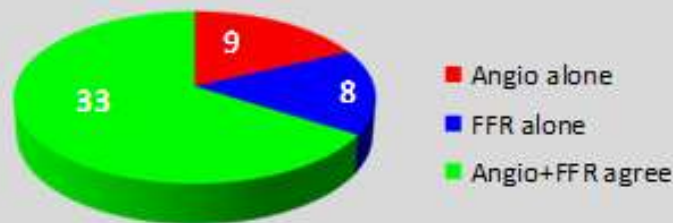
➤ In a total of 36 (ie 18%) cases the angiogram would have got indication for left anterior descending revascularisation wrong according to FFR...

### Circumflex



➤ In a total of 27 (ie 13.5%) cases the angiogram would have got indication for circumflex revascularisation wrong according to FFR

### Right Coronary



➤ In a total of 17 (ie 8.5%) cases the angiogram would have got indication for right coronary artery revascularisation wrong according to FFR