

# Supplementary data

## Supplementary Appendix 1. CONSORT checklist.

### Reporting checklist for randomised trial.

Based on the CONSORT guidelines.

#### Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the CONSORT reporting guidelines, and cite them as:

Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials

		Reporting Item	Page Number
<b>Title and Abstract</b>			
Title	<a href="#">#1a</a>	Identification as a randomized trial in the title.	1
Abstract	<a href="#">#1b</a>	Structured summary of trial design, methods, results, and conclusions	1
<b>Introduction</b>			
Background and objectives	<a href="#">#2a</a>	Scientific background and explanation of rationale	2
Background and objectives	<a href="#">#2b</a>	Specific objectives or hypothesis	2
<b>Methods</b>			
Trial design	<a href="#">#3a</a>	Description of trial design (such as parallel,	2

		factorial) including allocation ratio.	
Trial design	<a href="#">#3b</a>	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	<a href="#">#4a</a>	Eligibility criteria for participants	2
Participants	<a href="#">#4b</a>	Settings and locations where the data were collected	2
Interventions	<a href="#">#5</a>	The experimental and control interventions for each group with sufficient details to allow replication, including how and when they were actually administered	2
Outcomes	<a href="#">#6a</a>	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	2-3
Sample size	<a href="#">#7a</a>	How sample size was determined.	3
Sample size	<a href="#">#7b</a>	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomization - Sequence generation	<a href="#">#8a</a>	Method used to generate the random allocation sequence.	
n/a (in primary outcome publication)			
Randomization - Sequence generation	<a href="#">#8b</a>	Type of randomization; details of any restriction (such as blocking and block size)	
n/a (in primary outcome publication)			
Randomization - Allocation concealment mechanism	<a href="#">#9</a>	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	n/a (in primary outcome publication)
Randomization - Implementation	<a href="#">#10</a>	Who generated the allocation sequence, who enrolled participants, and who assigned	n/a (in primary outcome publication)

		participants to interventions	publication)
Blinding	<a href="#">#11a</a>	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how.	n/a
Blinding	<a href="#">#11b</a>	If relevant, description of the similarity of interventions	n/a
Statistical methods	<a href="#">#12a</a>	Statistical methods used to compare groups for primary and secondary outcomes	3
Statistical methods	<a href="#">#12b</a>	Methods for additional analyses, such as subgroup analyses and adjusted analyses	3
Outcomes	<a href="#">#6b</a>	Any changes to trial outcomes after the trial commenced, with reasons	n/a

## Results

Participant flow diagram (strongly recommended)	<a href="#">#13a</a>	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	3
Participant flow	<a href="#">#13b</a>	For each group, losses and exclusions after randomization, together with reason	3
Recruitment	<a href="#">#14a</a>	Dates defining the periods of recruitment and follow-up	3
Recruitment	<a href="#">#14b</a>	Why the trial ended or was stopped	3
Baseline data	<a href="#">#15</a>	A table showing baseline demographic and clinical characteristics for each group	Supplementary Data
Numbers analysed	<a href="#">#16</a>	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	3
Outcomes and estimation	<a href="#">#17a</a>	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	3

Outcomes and estimation	<a href="#">#17b</a>	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	3
Ancillary analyses	<a href="#">#18</a>	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	3
Harms	<a href="#">#19</a>	All important harms or unintended effects in each group (For specific guidance see CONSORT for harms)	n/a
<b>Discussion</b>			
Limitations	<a href="#">#20</a>	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	6
Interpretation	<a href="#">#22</a>	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	3
Registration	<a href="#">#23</a>	Registration number and name of trial registry	1
Generalisability	<a href="#">#21</a>	Generalisability (external validity, applicability) of the trial findings	6
<b>Other information</b>			
Interpretation	<a href="#">#22</a>	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	6
Registration	<a href="#">#23</a>	Registration number and name of trial registry	1
Protocol	<a href="#">#24</a>	Where the full trial protocol can be accessed, if available	n/a
Funding	<a href="#">#25</a>	Sources of funding and other support (such as supply of drugs), role of funders	1

Notes:

- 8a: n/a (in primary outcome publication)

- 8b: n/a (in primary outcome publication)
- 9: n/a (in primary outcome publication)
- 10: n/a (in primary outcome publication) The CONSORT checklist is distributed under the terms of the Creative Commons Attribution License CC-BY. This checklist was completed on 16. April 2023 using <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)

**Supplementary Table 1. Patient demographics.**

	Provisional (n=103)	Culotte (n=97)
Age (years)	62.9 (10.8)	63.5 (12.1)
Female	16 (15.5%)	21 (21.6%)
BMI	28.1 (4.8)	27.8 (4.9)
Diabetes mellitus	26 (25.2%)	30 (30.9%)
Hypertension	65 (63.1%)	66 (68.0%)
Current or past smoker	58 (56.3%)	49 (50.5%)
Family history	49 (47.6%)	48 (49.5%)
Hypercholesterolaemia	72 (69.9%)	70 (72.2%)
Creatinine >200 mmol/L	0 (0%)	1 (1.0%)
Previous MI	40 (38.8%)	40 (41.2%)
Previous PCI	41 (39.8%)	40 (41.2%)
Previous CABG	6 (5.8%)	2 (2.1%)
Peripheral vascular disease	6 (5.8%)	8 (8.2%)
Previous CVA	6 (5.8%)	3 (3.1%)
Left ventricular function		
Good (EF >50%)	59 (57.3%)	65 (67.0%)
Moderate (30-50%)	18 (17.5%)	20 (20.6%)
Poor (<30%)	1 (1.0%)	2 (2.1%)
Unknown	25 (24.3%)	10 (10.3%)
Presentation		
Stable	71 (68.9%)	66 (68.0%)
Acute coronary syndrome	32 (31.1%)	31 (32.0%)
Diseased territories >70%		
One vessel	77 (76.2%)	61 (65.6%)
Two vessel	18 (17.8%)	27 (29.0%)
Three vessel	6 (5.9%)	5 (5.4%)
Site of bifurcation disease		
LAD	80 (78.4%)	75 (77.3%)
Circumflex	16 (15.7%)	18 (18.6%)
RCA	6 (5.9%)	4 (4.1%)
Medina		
1.1.1	83 (80.6%)	66 (68.0%)
1.0.1	6 (5.8%)	7 (7.2%)
0.1.1	12 (11.7%)	23 (23.7%)
Adverse lesion features		
Calcification $\geq$ moderate	20 (19.4%)	17 (17.5%)
Tortuosity $\geq$ moderate	10 (9.7%)	15 (15.5%)
Values are mean (SD) or n (% known)		

**Supplementary Table 2.** Procedural details.

	Provisional (n=103)	Culotte (n=97)	p
Access site			0.36
Femoral	38 (36.9%)	42 (43.3%)	
Radial	65 (63.1%)	55 (56.7%)	
Sheath size			0.55
6F	75 (72.8%)	63 (64.9%)	
7F	17 (16.5%)	20 (20.6%)	
8F	11 (10.7%)	13 (13.4%)	
Lesion length (mm)			
Main vessel	18 (6.8)	17.9 (8.8)	0.97
Side branch	9.7 (7.1)	10.8 (7.3)	0.31
Main vessel stented	103 (100%)	96 (99%)	0.49
Stent diameter (mm)	3.06 (0.32)	3.03 (0.33)	0.39
Stent length (mm)	23.4 (4.8)	22.9 (5.1)	0.35
Side branch stented	16 (16%)	94 (97%)	<0.001
Stent diameter (mm)	2.61 (0.29)	2.72 (0.25)	0.13
Stent length (mm)	19.9 (6.8)	20.7 (5.5)	0.61
Total stented length (mm)	33.6 (17)	51.8 (20)	<0.001
Total stent number	1.6 (0.8)	2.5 (0.7)	<0.001
Kissing balloon inflation	97 (94%)	93 (96%)	0.75
Additional lesion(s) treated	24 (23.3%)	39 (40.2%)	0.01
Procedural success	100 (97%)	95 (98%)	0.99
Procedural time (min)	67.8 (25.6)	82.5 (38.8)	<0.001
Fluoroscopy time (min)	20.1 (10.1)	26.6 (17.1)	<0.001
Diamentor (cGy.cm <sup>2</sup> )	11447 (8866)	18362 (31779)	0.035
Contrast volume (mL)	245.9 (98.8)	269.3 (120.3)	0.13
Procedural cost (Euros)	2257	3263	<0.001
Values are mean (SD) or n (% known)			