Supplemental material

The treatment effects of systematic two-stent and provisional stenting techniques in patients with complex coronary bifurcation lesions: Rationale and design of a prospective, randomized, and multicenter DEFINITION Ⅱ Trial

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Zhang JJ and Gao XF contributed equally to this work.

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[26]Jintan People's Hospital, Jintan, China;

[27]Wuxi Third People 's Hospital, Wuxi, China;

[28]Daqing Oil General Hospital, Daqing, China;

[29]The Second Hospital of Shandong University, Ji'nan, China;

[30]Xinyang Central Hospital, Xinyang, China;

[31]Fujian Union Hospital, Fuzhou, China;

[32]Jilin Heart Hospital, Changchun, China;

[33]Otamendi Hospital, Buenos Aires, Argentina;

[34]Chuzhou First People 's Hospital, Chuzhou, China;

[35]Huainan Xinhua Hospital, Huainan, China;

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Appendix 1. Definitions of major study endpoints

Endpoint	Definition
Death	● **Cardiovascular death** includes sudden cardiac death, death due to acute myocardial infarction (MI), arrhythmia, heart failure, stroke, other cardiovascular causes, or bleeding ● **Non-cardiovascular death** is defined as any death with known cause not of cardiac or vascular cause ● All deaths are considered cardiac in origin unless a non-cardiac cause is confirmed clinically or at autopsy.
Myocardial infarction	**Post-procedure MI**: occurrence within 48 hours after PCI ● Patients with normal baseline CK-MB: the peak CK-MB measured within 48 hours of the procedure rises to ≥ 10 × upper reference limit (URL), or to ≥ 5 × URL with new pathologic Q-waves in at least 2 contiguous leads or new persistent left bundle branch block (LBBB) ● Patients with elevated baseline CK-MB in whom the biomarker levels are stable or falling: the CK-MB rises by an absolute increment equal to those levels recommended above from the most recent pre-procedure level **Spontaneous MI**: occurrence more than 48 hours after PCI ● The rise of cardiac biomarkers (CK-MB or troponin) > 1x URL, with one of the follows: ➢ Evidence of prolonged ischemia as demonstrated by prolonged chest pain ➢ Ischemic ST-segment changes or new pathological Q waves ➢ Angiographic evidence of a flow limiting complication ➢ Imaging evidence of new loos of viable myocardium or new regional wall motion abnormality **Target vessel MI:** spontaneous MI associated with target vessel (including main vessel [MV] and side branch [SB]), which was identified by electrocardiographic changes or coronary angiography. Each MI will also be classified as ST-segment elevation MI (STEMI) and non-ST-segment elevation MI (NSTEMI)
Revascularization	**Target lesion revascularization (TLR)** ● Repeat revascularization (including PCI and coronary artery bypass grafting) for target lesions (including MV and SB), in the presence of symptoms or objective signs of ischemia **Target vessel revascularization (TVR)** ● Repeat revascularization (including PCI and coronary artery bypass grafting) for target vessels (including MV and SB), in the presence of symptoms or objective signs of ischemia **Target vessel non-target lesion revascularization** ● Target vessel non-target lesion consists of a lesion in the epicardial vessel/branch/graft that contains the target lesion; however, this lesion is outside of the target lesion by at least 5 mm distal or proximal to the target lesion determined by quantitative coronary angiography
Stent thrombosis	Academic Research Consortium (ARC) classification **Definite stent thrombosis** ● Symptoms suggestive of an acute coronary syndrome and angiographic or pathological confirmation of stent thrombosis

	Probable stent thrombosis ● Unexplained death within 30 days or target vessel myocardial infarction without angiographic confirmation of stent thrombosis **Possible stent thrombosis** ● Any unexplained death after 30 days Stent thrombosis will also be classified as acute stent thrombosis (0–24 hours after PCI), subacute stent thrombosis (24 hours-30 days), late stent thrombosis (31 days–1 year), or very late stent thrombosis (>1 year)
Bleeding	Bleeding Academic Research Consortium (BARC) classification **Type 0**: no bleeding **Type 1**: bleeding that is not actionable and doses not cause the patient to seek unscheduled performance of studies, hospitalization, or treatment **Type 2**: any overt, actionable sign of hemorrhage that doses not fit the criteria for 3, 4, or 5 **Type 3**: ● **Type 3a**: overt bleeding with hemoglobin drop of 3 to 5 g/dl; any transfusion with overt bleeding ● **Type 3b**: overt bleeding with hemoglobin drop ≥ 5g/dl; cardiac tamponade; bleeding requiring surgical intervention for control; bleeding requiring intravenous vasoactive agents ● **Type 3c**: intracranial hemorrhage; intraocular bleeding compromising vision **Type 4**: CABG-related bleeding **Type 5**: fatal bleeding
Stroke	Global or focal cerebral, spinal cord, or retinal injury resulting in acute neurological dysfunction and was further classified into ischemic and hemorrhagic stroke

Appendix 2. Trial organization

Principal investigator:

Shao-Liang Chen, Nanjing First Hospital, Nanjing Medical University

Steering committee:

Shao-Liang Chen, Gregg W Stone, Bo Xu , Imad Sheiban, Ya-ling Han

Core laboratory:

Nanjing Heart Center

Study statistician:

School of Public Health, Nanjing Medical University

Data and safety monitoring committee:

Bao-Xiang Duan, Lin Lin, Ji Yong, Linda Lison

Participating hospitals and collaborators of DEFINITION Ⅱ trial:

1. Nanjing First Hospital, Nanjing Medical University, Nanjing, China;
2. The General Hospital of Shenyang Military, Shenyang, China;
3. Xijing Hospital, 4th Military Medical University, Xi'an, China;
4. Medicine Siriraj Hospital, Bangkok, Thailand;
5. Taicang People's Hospital, Taicang, China;
6. Anhui Provincial Hospital, Hefei, China;
7. Huainan Eastern Hospital, Huainan, China;
8. Yixin People's Hospital, Yixin, China;
9. Cangzhou Central Hospital, Cangzhou, China;
10. Binawaluya Cardiac Center, Jakarta, Indonesia;
11. Guangzhou Red Cross Hospital, Guangzhou, China;
12. Shanghai Ruijin Hospital, Shanghai, China;
13. Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China;
14. Medistra Hospital, University of Indonesia, Jakarta, Indonesia;
15. Gansu Provincial Hospital, Lanzhou, China;
16. Beijing Anzhen Hospital, Capital Medical University, Beijing, China;
17. Changshu First People's Hospital, Changshu, China;
18. Cheng-Hsin General Hospital, Taipei, China;
19. Zhangjiagang First People's Hospital, ZhangjiaGang, China;
20. Changzhou Hospital of Traditional Chinese Medicine, Changzhou, China;
21. Jiangxi Provincial People's Hospital, Nanchang, China;
22. Bangkok General Hospital, Bangkok, Thailand;
23. Xia'Men Zhongshan Hospital, Xia'Men, China;
24. Huainan First People's Hospital, Huainan, China;
25. Jintan People's Hospital, Jintan, China;
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28. The Second Hospital of Shandong University, Ji'nan, China;

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30. Fujian Union Hospital, Fuzhou, China;
31. Jilin Heart Hospital, Changchun, China;
32. Otamendi Hospital, Buenos Aires, Argentina;
33. Chuzhou First People 's Hospital, Chuzhou, China;
34. Huainan Xinhua Hospital, Huainan, China;
35. Bangle Hospital, Bangkok, Thailand;
36. Huai'an Second People's Hospital, Huai'an, China;
37. Qingdao Fuwai Hospital, Qingdao, China;
38. The Affiliated Hospital of Guangdong Medical University, Guangdong, China;
39. University of Turin, Turin, Italy;
40. The Affiliated Hospital of Xuzhou Medical University, Xuzhou, China;
41. Xuyi People's Hospital, Xuyi, China;
42. Wuxi Huishan District People's Hospital, Wuxi, China;
43. Anqing First People's Hospital, Anqing, China;
44. Liyang Hospital of Traditional Chinese Medicine, Liyang, China;
45. Lianyungang Hospital of Traditional Chinese Medicine, Lianyungang, China;

Appendix 3. Institutional Review Boards

南京市第一医院伦理委员会审批件

编号：KY20141128-01

科研项目名称	比较 DK Crush 技术和 Provision Stenting 技术处理复杂分叉病变的前瞻性、随机对照研究（DEFINATION-2）		
项目来源	中办者发起	CRO	无
申请科室	心内科	项目负责人	陈绍良
审查时间	2014 年 11 月 28 日	审查地点	南京市第一医院多媒体教室
审查方式	■会议审查　□快速审查		
审批材料	详见附件审批材料目录		

伦理委员会成员

姓名	性别	单位部门	职称	伦理职务	签到
沈海琦	男	南京市第一医院骨科	主任医师	主任委员	
马俊	男	南京市第一医院党委	政工师	副主任委员	
陈亚新	女	南京医科大学医政学院	副教授	副主任委员	
刘晓东	男	中国药科大学	教授	副主任委员	
夏京胜	男	江苏三法律师事务所	律师	委员	
孙辉	男	南京市建邺区信访局	公务员	委员	
娄晟	女	南京市第一医院药剂科	主任药师	委员	
张林	男	南京市第一医院科技处	主治医师	委员	
朱怀刚	男	南京市第一医院教育处	主管技师	委员	
赵太宏	男	南京市第一医院医务处	副主任医师	委员	
陈玉红	女	南京市第一医院护理部	主任护师	委员	

出席人数	应到人数 11 人、实到人数 9 人，其中：投票人数 9 人，回避人数 0 人。
投票结果	同意（ 8 ）修改后同意（ 1 ）修改后重审（ 0 ） 不同意（ 0 ） 终止或暂停（ 0 ）

1

审查意见：

本伦理委员会的职责、人员组成、操作程序及记录遵循 ICH-GCP、中国 GCP 和中国相关法律。根据卫生部《涉及人的生物医学研究伦理审查办法(试行 (2007))》、SFDA 《药物临床试验质量管理规范(2003)》、《医疗器械临床试验规定 (2004)》、《赫尔辛基宣言》和 《人体生物医学研究国际道德指南》的伦理原则进行审查。

□非同意性意见：

按审查意见修改后的文件，或对审查意见不同观点的陈诉，请提交"复审申请"，方案/知情同意书 请注明新的版本号和版本日期，并以下划线方式标注修改部分，报伦理委员会审查，经批准后执行。

具体修改意见：

☑同意性意见：

经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书、招募材料开展本项研究。

请遵循 GCP 原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权利。

研究开始前，请申请人完成临床试验注册。

研究过程中若变更主要研究者，对临床研究方案、知情同意书、招募材料等的任何修改，请申请人提交修正案审查申请。

发生严重不良事件，请申请人及时提交严重不良事件报告。

请按照伦理委员会规定的年度跟踪审查频率申请人在截止日期前 1 个月提交研究进展报告

申办者应当向组长单位伦理委员会提交各中心研究进展的汇总报告，当出现任何可能显著影响试验进行或增加受试者危险的情况时，请申请人及时向伦理委员会提交书面报告。

研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验规定而未让受试者退出研究，给予错误治疗或剂量，给予方案禁止的合并用药等没有遵从方案开展研究的情况;或可能对受试者的权益/健康以及研究的科学性造成不良影响等违背 GCP 原则的情况，请监查员/研究者提交违背方案报告。

申请人暂停或提前终止临床研究，请及时提交暂停/终止研究报告。 完成临床研究，请申请人提交结题报告。

具体审查意见：

跟踪审查频率：□半年 ☑一年 □其他

本批件有效期为1年（自批准之日起），逾期未实施的，则自行废止。

联系电话：025-52271039

审 批 结 论

同意(✓) 修改后同意( )修改后重审( ) 不同意( ) 终止或暂停( )

主任委员（签名）：

2014年1月28日

南京市第一医院伦理委员会快速审批件

编号：KY20141128-01-KS-01

科研项目名称	比较双支架术和必要时分支支架术治疗冠状动脉复杂分叉病变的一项前瞻性，多中心，随机对照研究（DEFINATION-2）		
项目来源	申办者发起	CRO	无
申请科室	心内科	项目负责人	陈绍良
审批材料	1、修正案审查申请表 2、研究方案（版本 1.1，日期 2015-12-08） 3、病例报告表（版本 1.1，日期 2015-12-08） 4、知情同意书（版本 1.1，日期 2015-12-08）		

快审人员签名			
签名			
职务	主任委员	委员	

审批结论

同意(√)　修改后同意(　)　不同意(　)　终止或暂停(　)

转为会审 (　)

说明：

主任委员或授权人（签名）：

2015年12月16日

声明	本伦理委员会的职责、人员组成、操作程序及记录遵循 ICH-GCP、中国 GCP 和中国相关法律。

南京市第一医院伦理委员会快速审批件

编号：KY20141128-01-KS-01

科研项目名称	比较双支架术和必要时分支支架术治疗冠状动脉复杂分叉病变的一项前瞻性，多中心，随机对照研究（DEFINATION-2）		
项目来源	申办者发起	CRO	无
申请科室	心内科	项目负责人	陈绍良
审批材料	1、修正案审查申请表 2、研究方案（版本 1.2，日期 2016-02-25） 3、病例报告表（版本 1.2，日期 2016-02-25） 4、知情同意书（版本 1.2，日期 2016-02-25）		

快审人员签名			
签名			
职务	主任委员	委员	

审批结论

同意（√）　修改后同意（　）　不同意（　）　终止或暂停（　）

转为会审（　）

说明：

主任委员或授权人（签名）：

2016年3月9日

声明	本伦理委员会的职责、人员组成、操作程序及记录遵循 ICH-GCP、中国 GCP 和中国相关法律。

Appendix 4. SPIRIT 2013 Checklist

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	5
	2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	3	Date and version identifier	16
Funding	4	Sources and types of financial, material, and other support	16
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	15-16
	5b	Name and contact information for the trial sponsor	16
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	16
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	9-10
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
	6b	Explanation for choice of comparators	4
Objectives	7	Specific objectives or hypotheses	4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	___5_____
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	____5_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	___5-6____
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	____6_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	____6_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	___6-7____
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	____7_____
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	____7_____
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	____8_____
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	___n/a____

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	____5_____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	___5_____

Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	5
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	5,7
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	7
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	n/a
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	n/a
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	8-9
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	9
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	8-9

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	9
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	n/a

Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	___9-10___
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	___9_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	___n/a____
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	___9_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	___9_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	___n/a____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	___16_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	___9,16___
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	___n/a____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	___9_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	___9,16___
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	___n/a____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	___9_____
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	___n/a____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.