Appendix 1

MRI-guided thrOmbolysis for Stroke bEyond Time Window by TNK (ROSE-TNK): a prospective, randomized, blinded-endpoint, multicentre trial

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APPENDIX I: CONSORT 2010 CHECKLIST FOR TRAIL

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	2
	2b	Specific objectives or hypotheses	2
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	2
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	2
	4b	Settings and locations where the data were collected	2
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	2
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	2-3
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	NA
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	2
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	2
Allocation concealment mechanism	9	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	2
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	2

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	2
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	3
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	3
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	3
	13b	For each group, losses and exclusions after randomisation, together with reasons	3
Recruitment	14a	Dates defining the periods of recruitment and follow-up	3
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	4
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	3
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	3
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	3
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	3-4
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	5-6
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	4
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	6
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	Appendix 2
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	6

APPENDIX II**: COMMITTEE MEMBERS**

Steering Committee

- Yi-Long Wang (Chair, Tiantan Hospital, Capital Medical University, Beijing, China)
- Hui-Sheng Chen (Chief Investigator, General Hospital of Northern Theater Command, Shenyang, China)
- Yu-Tong Ma (Co-Principal Investigator, Beipiao Central Hospital, Beipiao, China)
- Hong Zhang (Co-Principal Investigator, Liaoning Health Industry Group Fukuang General Hospital, Fushun, China)
- Chang-Hao Jiang (Co-Principal Investigator, Lvshunkou Traditional Chinese Medicine Hospital, Dalian, China)
- Ying-Jie Dai (Senior Trials Manager, General Hospital of Northern Theater Command, Shenyang, China)
- Lu Wang (Trials Manager, General Hospital of Northern Theater Command, Shenyang, China)
- Yu Cui (Medical Statistician, General Hospital of Northern Theater Command, Shenyang, China)

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- Xiao-Wen Hou (Department of Health Statistics, Shenyang Medical College, Shenyang, China)

Institution Human Research Ethics Committee

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- Ping Chen (Associate-chair, General Hospital of Northern Theater Command, Shenyang, China)
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APPENDIX III**: LIST OF INVESTIGATORS IN ROSE-TNK TRIAL**

* indicates principal investigator in the center.

† indicates blinded assessors in the outcome assessment.

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- Yi Zhang *
- Dan Cui †

APPENDIX IV: RECRUITMENT BY SITE IN ROSE-TNK TRAIL

Inclusion site	Number of patients randomized
Department of Neurology, Liaoning Health Industry Group Fukuang General Hospital	30
Department of Neurology, Beipiao Central Hospital	7
Department of Neurology, Lvshunkou Traditional Chinese Medicine Hospital	7
Department of Neurology, Liaoning Health Industry Group Fuxinkuang General Hospital	6
Department of Neurology, Haicheng Traditional Chinese Medicine Hospital	5
Department of Neurology, Huludao Second People's Hospital	4
Department of Neurology, Xiuyan county Central People's Hospital	4
Department of Neurology, The Dalinghe Affiliated Hospital of Jinzhou Medical University	4
Department of Neurology, Fuxin Center Hospital	3
Department of Neurology, Anshan Changda Hospital	3
Department of Neurology, Liaoning Health Industry Group Bengang General Hospital	3
Department of Neurology, Benxi Center Hospital	2
Department of Neurology, Tieling County Central Hospital	1
Department of Neurology, General Hospital of Northern Theater Command	1