CONSORT 2010 checklist

Section/topic	Item number	Checklist item
Title and abstract	1a	Identification as a randomized trial in the title – See title
	1b	Structured summary of trial design, methods, results, and conclusions – sentence 18-44
Introduction		
Background and objectives	2a	Scientific background and explanation of the rationale 47-62
	2b	Specific objectives or hypotheses – sentence 63-69
Methods		
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio – 72-80.
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Participants	4a	Eligibility criteria for participants – 84-85
	4b	Settings and locations where the data were collected 90-93
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered 100-131
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed 163 - 166
	6b	Any changes to trial outcomes after the trial commenced, with reasons

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Sample size	7a	How sample size was determined? 170-175
	7b	When applicable, explanation of any interim analyses and stopping guidelines - Not applicable
Randomization		
Sequence generation	8a	The method used to generate the random allocation sequence 78-83
	8b	Type of randomization; details of any restriction (such as blocking and block size) 78-83
Allocation concealment mechanism	9	The 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 – 78-83
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions 82
Blinding	11a	If done, who was blinded after assignment to interventions (e.g., participants, care providers, those assessing outcomes) and how 134
	11b	If relevant, description of the similarity of interventions
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes 179 - 185

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	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses Subgroup analyses were not done due to lack of power
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 analyzed for the primary outcome 196 -202
	13b	For each group, losses and exclusions after randomization, together with reasons Fig. 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up 198 and 203 - 204
	14b	Why the trial ended or was stopped
Baseline data	15	A table showing the baseline demographic and clinical characteristics for each group Table 1
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups The migration analyses were performed for all allocated patients for all images available, but some of the patients did not have a full data set (Fig.1)
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) 207 - 226

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	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)
Discussion		
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, the multiplicity of analyses 277 - 281
Generalizability	21	Generalizability (external validity, applicability) of the trial findings 283 - 292
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence 252 - 260
Other information		
Registration	23	Registration number and name of trial registry
Protocol	24	Where the full trial protocol can be accessed, if available 191 - 194
Funding	25	Sources of funding and other support (such as the supply of drugs), the role of funders No funding except from local hospitals research grant 313