

Supplementary Material for:

Efficacy of Dapagliflozin+Sitagliptin+Metformin versus Sitagliptin+Metformin in T2DM Inadequately Controlled on Metformin Monotherapy: A Multicentric Randomized Trial

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Table S1: Ethics approval details

List of Ethics Committee with date of Approval			
Sr. No.	Name of Ethics Committee	Name of Study Centre	Date of Approval
01	Rajarshee Chhatrapati Shahu Maharaj Govt. Medical College and Chhatrapati Pramila Raje General Hospital, Kolhapur Institutional Ethics Committee 2 (RCSMGMCIIEC2), Dasara Chowk, Town Hall, Bhausingji Road, Kolhapur-416002, Maharashtra. (ECR/703/Inst/MH/2015/RR-20)	Department of Medicine, Rajarshee Chhatrapati Shahu Maharaj Govt. Medical College and Chhatrapati Pramila Raje General Hospital, Dasara Chowk, Town Hall, Bhausingji Road, Kolhapur-416002, Maharashtra.	22-Jan-2022
02	Institutional Ethics Committee, Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur-302039, Rajasthan. (ECR/1222/Inst/RJ/2019/RR-22)	Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector-7, Vidyadhar Nagar, Jaipur-302039, Rajasthan.	25-Jan-2022
03	Vidhya Hospital and Trauma Centre Ethics Committee, Vidhya Hospitals & Trauma Centre, Harikansgadi, Mohanlalganj, Raebareli Road, Lucknow-226301, Uttar Pradesh. (ECR/1579/Inst/UP/2021)	Vidhya Hospitals & Trauma Centre, Harikansgadi, Mohanlalganj, Raebareli Road, Lucknow-226301, Uttar Pradesh.	27-Jan-2022
04	North East Healthcare Private Limited, Golf Course Ext. Road, Sushant Lok-II, Sector 56, Gurugram, Haryana-122011. (ECR/1282/Inst/HR/2019)	W Pratiksha Hospital, Golf Course Ext. Road, Sushant Lok II, Sector 56, Gurugram, Haryana-122011.	28-Jan-2022
05	Institutional Ethics Committee for Human Research, Medical College and Hospital, Kolkata, 88, College Street, Kolkata-700073, West Bengal. (ECR/287/Inst/WB/2013/RR-19)	Medical College and Hospital, Kolkata, MCH Building, 4 th Floor, 88 College Street, Kolkata-700073, West Bengal.	29-Jan-2022
06	Institutional Ethics Committee, Government Medical College and Government General Hospital (Old RMSGGH), Srikakulam-532001, Andhra Pradesh. (ECR/492/Inst/AP/2013/RR-20)	Department of Medicine, Government Medical College and Government General Hospital (Old RMSGGH), Srikakulam-532001, Andhra Pradesh.	31-Jan-2022
07	Institutional Ethics Committee, Ruby General Hospital, 576, Anandapur, Kasba, Golpark, EM Bypass, Kolkata-700107, West Bengal. (ECR/1202/Inst/WB/2019)	Ruby General Hospital Ltd., 576, Anandapur, Kasba, EM Bypass, Kolkata-700107, West Bengal.	02-Feb-2022
08	Institutional Ethics Committee, Aatman Hospital, 5, Anveshan Row House, Opp. Umiya Mata Mandir, Bopal-Ghuma Main Road, Bopal, Ahmedabad-380058, Gujarat. (ECR/1565/Inst/GJ/2021)	SMVS Swaminarayan Hospital, Gandhinagar-Ahmedabad Road, Beside Swaminarayan Dham, Urjanagar 1, Randesan, Gandhinagar-382007, Gujarat.	04-Feb-2022
09	Redkar Hospital Institutional Ethics Committee (RHIEC), Redkar Hospital and Research Centre, Mumbai-Goa Highway, Oxelbag, Dhargal, Pernem, Goa-403513. (ECR/902/Inst/GA/2018/RR-21)	Redkar Hospital and Research Centre, Mumbai-Goa Highway, Oxelbag, Dhargal, Tal-Pernem, Goa-403513.	11-Feb-2022
10	Ethics Committee, Down Town Hospital, 6th Floor, 1st Building, G.S. Road, Dispur, Guwahati-781006, Assam. (ECR/549/Inst/AS/2014/RR-20)	Down Town Hospital, Dispur, G.S. Road, Guwahati-781006, Assam.	25-Feb-2022
11	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan. (ECR/1156/Inst/RJ/2018/RR-22)	Department of Medicine, Jawahar Lal Nehru (J.L.N) Medical College, Kala Bagh, Ajmer-305001, Rajasthan.	11-Feb-2022
12	Ethics Committee, GSVM Medical College, Room No-125, 1 st Floor, Swaroop Nagar, Kanpur-208002, Uttar Pradesh. (ECR/680/Inst/UP/2014/RR-20)	Post Graduate Department of Medicine, GSVM Medical College, Swaroop Nagar, Kanpur-208002, Uttar Pradesh.	16-Mar-2022

Table S2: CONSORT checklist



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract	1a	Identification as a randomised trial in the title	1, 6
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	6
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	8, 9
	2b	Specific objectives or hypotheses	8, 9
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	9
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	9
Participants	4a	Eligibility criteria for participants	9
	4b	Settings and locations where the data were collected	9
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9, 10
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size	7a	How sample size was determined	12
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	10
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	10
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	10
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	10
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	10
		assessing outcomes) and how	-
Statistical methods	11b	If relevant, description of the similarity of interventions	-
	12a	Statistical methods used to compare groups for primary and secondary outcomes	11
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11
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	13
	13b	For each group, losses and exclusions after randomisation, together with reasons	13
Recruitment	14a	Dates defining the periods of recruitment and follow-up	12
	14b	Why the trial ended or was stopped	-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	14, Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	14
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)	14, 15
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	14, 15
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, multiplicity of analyses	14
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	14
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14, 15
Other information			
Registration	23	Registration number and name of trial registry	19
Protocol	24	Where the full trial protocol can be accessed, if available	19
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	19

Table S3: Center-wise patient details

Center Id	Number of patients screened	Number of patients with screen failure	Number of patients with consent withdrawn	Number of patient s randomized	Number of dropout	Number of completed patients
1	25	0	1	24	1	23
2	20	2	0	18	1	17
3	19	1	0	18	0	18
4	25	1	0	24	1	23
5	28	3	1	24	1	23
6	35	3	2	30	2	28
7	18	0	0	18	0	18
8	30	5	1	24	1	23
9	19	1	0	18	0	18
10	26	2	0	24	2	22
11	32	4	0	28	1	27
12	29	5	0	24	1	23
	306	27	5	274	11	263