

ISRCTN95532888 - DIM-05520-001 (SystUp)

Requirement for study results publication:

1. Participant Flow: A flow diagram showing participants involved at each stage of the study (namely enrolment, intervention allocation, follow-up, and data analysis).
2. Baseline Characteristics: A tabular summary showing baseline demographic (age and gender) and clinical characteristics of the participants.
3. Outcome Measures: A tabular summary of the outcome measures listed in the ISRCTN record. Please ensure to list your primary outcome measures in a tabular format and provide your secondary outcome measures in a separate table if available.
4. Adverse Events: a tabular summary of all anticipated and unanticipated serious adverse events (life-threatening) and anticipated and unanticipated other adverse events (non-life threatening) which will include a description of the adverse event and the number of participants affected. If there were no adverse events associated with your trial then please include a statement to the effect of "There were no adverse events associated with this trial."

Participant Flow

A total of 4242 subjects from Colombia, India and Malaysia were enrolled and included in the Full Analysis Set.

Country	Overall N = 4242	
	n	%
Colombia	208	4.9
India	3945	93.0
Malaysia	89	2.1

Baseline Characteristics

Characteristics	Parameters or categories	<65 years N = 2709		≥65 years N = 1532		Overall N = 4242	
		Value or n	%	Value or n	%	Value or n	%
Age (Years)	n (Missing)	2709 (0)	-	1532 (0)	-	4241 (1)	-
	Mean	56.9	-	71.9	-	62.3	-
	SD	4.64	-	5.69	-	8.81	-
	Median	57	-	71	-	61	-
	Q1 ; Q3	53 ; 61	-	68 ; 75	-	55 ; 68	-
	Min ; Max	26 ; 64	-	65 ; 105	-	26 ; 105	-
Gender	Female	1174	43.3	587	38.3	1762	41.5
	Male	1532	56.6	943	61.6	2475	58.3
	Missing	3	0.1	2	0.1	5	0.1
BMI (kg/m ²)	n (Missing)	2690 (19)	-	1523 (9)	-	4214 (28)	-
	Mean	27.0	-	26.3	-	26.7	-
	SD	5.09	-	4.68	-	4.96	-
	Median	26.2	-	26	-	26.1	-
	Q1 ; Q3	24 ; 29	-	23 ; 29	-	24 ; 29	-
	Min ; Max	10 ; 67	-	15 ; 62	-	10 ; 67	-

BMI: body mass index; N: total number of subject; n: number of subjects in a given category; % = n/N; SD: standard deviation; Q: quartile; Min: minimum; Max: maximum.

Outcome Measures

Systolic blood pressure at the study visit

Main objective was to assess the level of systolic blood pressure in older patients with uncontrolled systolic blood pressure (≥ 140 mm Hg)

Characteristics	Statistics	<65 years N = 2709	≥ 65 years N = 1532	Overall N = 4242
Mean Systolic Blood Pressure (mmHg)	n (Missing)	2709 (0)	1532 (0)	4242 (0)
	Mean	155.5	159.1	156.8
	SD	12.74	13.88	13.27
	Median	153	160	155
	Q1 ; Q3	147 ; 160	150 ; 168	148 ; 163
	Min ; Max	118 ; 220	110 ; 250	110 ; 250
Mean Diastolic Blood Pressure (mmHg)	n (Missing)	2709 (0)	1532 (0)	4242 (0)
	Mean	90.1	89.1	89.7
	SD	9.30	10.83	9.89
	Median	90	90	90
	Q1 ; Q3	84 ; 96	81 ; 96	84 ; 96
	Min ; Max	44 ; 120	45 ; 154	44 ; 154

Stroke risk at the study visit

Characteristics	Statistics	<65 years (n=2709)	≥ 65 years (n=1532)	Overall (n=4242)
5-year stroke risk (%)	n (Missing)	2661 (48)	1470 (62)	4132 (110)
	Mean (SD)	7.6 (7.95)	16.4 (16.02)	10.7 (12.24)
	Median	4.6	10.6	6.3
	Q1 ; Q3	3 ; 8	6 ; 20	4 ; 13
	Min ; Max	0 ; 76	1 ; 100	0 ; 100
10-year stroke risk (%)	n (Missing)	2661 (48)	1470 (62)	4132 (110)
	Mean (SD)	16.8 (15.83)	33.4 (24.02)	22.7 (20.73)
	Median	11.0	24.8	14.9
	Q1 ; Q3	7 ; 20	15 ; 44	9 ; 29
	Min ; Max	1 ; 97	1 ; 98	1 ; 98

Secondary objectives was:

- to illustrate the correlation between stroke risk (calculated using the Stroke Riskometer™) and level of systolic blood pressure in patients with uncontrolled systolic blood pressure and
- to assess that there is no correlation between diastolic blood pressure and the risk of stroke

Primary Measures	Characteristics	Statistics	<65 years N = 2709	≥ 65 years N = 1532	Overall N = 4242
Systolic Blood Pressure, mmHg	5-Year Stroke Risk	n (Missing)	2661 (48)	1470 (62)	4132 (110)
		r	0.2185	0.1655	0.2134
	10-Year Stroke Risk	n (Missing)	2661 (48)	1470 (62)	4132 (110)
		r	0.2296	0.1915	0.2410
Diastolic Blood Pressure,	5-Year Stroke Risk	n (Missing)	2661 (48)	1470 (62)	4132 (110)
		r	0.0538	0.0346	0.0230

Primary Measures	Characteristics	Statistics	<65 years N = 2709	≥65 years N = 1532	Overall N = 4242
mmHg	10-Year Stroke Risk	n (Missing)	2661 (48)	1470 (62)	4132 (110)
		r	0.0539	0.0023	0.0085

Antihypertensive use

Characteristics	Parameters or categories	<65 years N = 2709		≥65 years N = 1532		Overall N = 4242	
		n	%	n	%	n	%
Antihypertensive medication	Yes	2701	99.7	1529	99.8	4231	99.7
	No	8	0.3	2	0.1	10	0.2
	Missing	0	-	1	0.1	1	0.0

Class	<65 years		≥65 years		Overall	
	N=2709	%	N=1532	%	N=4242	%
ACE inhibitor	527	19,45%	273	17,82%	800	18,86%
Angiotensin receptor blocker	1277	47,14%	804	52,48%	2081	49,06%
β-blocker	609	22,48%	428	27,94%	1037	24,45%
Calcium channel blocker	1457	53,78%	855	55,81%	2313	54,53%
Diuretic	1234	45,55%	752	49,09%	1987	46,84%
α-blocker or centrally acting agent	35	1,29%	19	1,24%	54	1,27%

Adverse Events

There were no adverse events reported during this study.