

2SRT: Serbian Smoking Reduction/Cessation Trial

Flow chart of scheduled events (clinical visits highlighted). Visits are to be scheduled within a -1/+1 week “window”.

Scheduled activity	Base-line visit	Weeks after randomization: 1 ¹	2	6	9 ¹	12	13-16	18	24	25-28	30	36	37-40	42	48	49-52	At completion or discontinuation for any reason before week 48
Assessment of eligibility, informed consent, medical & smoking history, randomization, etc.	x																
CO in exhaled air	x		x	x		x		x	x		x	x		x	x		
Lung function test	x					x			x			x			x		
Blood tests, etc ²	x					x			x			x			x		
Self-reported smoking status ³	x	x		x	x	x		x	x		x	x		x	x		
Height, weight ⁴	x			x		x			x			x			x		
Blood pressure	x		x	x		x			x			x			x		
Fagerström test	x								x						x		
Assessment of compliance		x	x	x	x			x	x		x	x		x	x		
Assessment of AE		x	x	x	x			x	x		x	x		x	x		
Information to participants about test results by mail (or telephone)							x			x			x		x	x	
Termination case report ⁵																	x

1. Telephone contact

2. Including extra 30-50 ml blood and sampling of buccal cells for exploratory analyses at selected study sites, see separate protocol.

3. Based on information in the participants' study diaries. At week 1, 2, and 6 self-reported average number of smoked cigarettes per day refers to the situation during the preceding week. At week 12, 24, 36 and 48 the number will be recorded also for the entire preceding 4-week period. At week 36 and 48 the number will be recorded for the preceding 4-week, 12-week, and 24 week period.

4. Height to be measured only at baseline

5. To be filled in for all randomized patients either upon completion of trial at week 48, or at premature discontinuation for any reason