

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: NA

ACTIVE INGREDIENT: NA

Study No: NIS-CIN-XXX-2011/2

Developmental Phase: NA

Study Completion Date: 05 July 2013

Date of Report: 15 November 2013

OBJECTIVES:

(a) **Primary objective:**

Primary objective of the study is to obtain distribution and correlates of CIMT in subjects without established cardiovascular disease.

(b) **Secondary objectives:** To examine the association between:

- i. CIMT values and demographic characteristics
- ii. CIMT values and CVD risk factors

METHODS:

This was a non-interventional, prospective, multi-centric, cross-sectional study aimed to obtain the distribution of measurements of Carotid intima-media thickness (CIMT) in Indian subjects and involved 15 investigative sites across India. Total 1200 subjects were recruited considering 8 combinations for Age Groups and Gender. CIMT values were evaluated based on the age group, gender and risk factors of the subjects

RESULTS:

Overall 1229 (54.2% male) subjects were recruited with mean age of 48 years.

Primary endpoint results:

Mean CIMT value was 0.62 mm in male and 0.58 mm in female groups. CIMT values for different age groups are given in Table 1.

Age Group (years)	Mean CIMT value (n)	
	Male	Female
30-39	0.53 (187)	0.51 (153)
40-49	0.58 (170)	0.58 (137)
50-59	0.64 (149)	0.61(129)
60 and above	0.73 (119)	0.64 (113)
Total Population	0.62 (625)	0.58 (532)

Other Key results:

- The mean of maximum CIMT values data for both the genders, in all the age groups, did not follow normal distribution ($p < 0.05$, for Anderson-Darling statistics).
- At the 10% level of significance, using the forward selection method, age, systolic BP, triglycerides and LDL-cholesterol were found as the significant independent variables.
- The regression coefficients for age and systolic BP were significantly different from zero at 5% level of significance.
- A unit increase in the age parameter, 0.005-unit increase in the CIMT value can be expected. Similarly, for a unit increase in the systolic BP, 0.001-unit increase in CIMT value can be expected.

Abbreviations:

CIMT: Carotid Intima Media Thickness; CVD: cardiovascular Disease; LDL: Low Density Lipoprotein; BP: Blood Pressure