









# Major Entry Criteria

- Histologically or cytologically confirmed ATC
  - Central pathology review
- ECOG PS  $\leq 2$
- Life expectancy  $\geq 12$  wks
- May have received prior surgery, radiation  $\pm$  chemotherapy
- Stratified by geographic region, age, prior surgery



# Results

- 40 sites in 11 countries
- No DSMB-mandated changes to protocol or procedures
- Comparable proportion of patients received 6 cycles on both arms
- HR: 0.72 (0.43, 1.20)
- Median survival (95% CI)
  - 5.2 mos (3.1, 9.0) vs. 4.0 mos (2.8, 6.2)
- 1-Yr survival (95% CI)
  - 25.5% CA4P + C/P (15, 38) vs. 8.7% C/P (2, 24)
- Enrollment closed at 80 patients
  - Unsustainably low accrual
- All patients received protocol specified treatments and were followed for survival.
- Final analysis performed and presented here.

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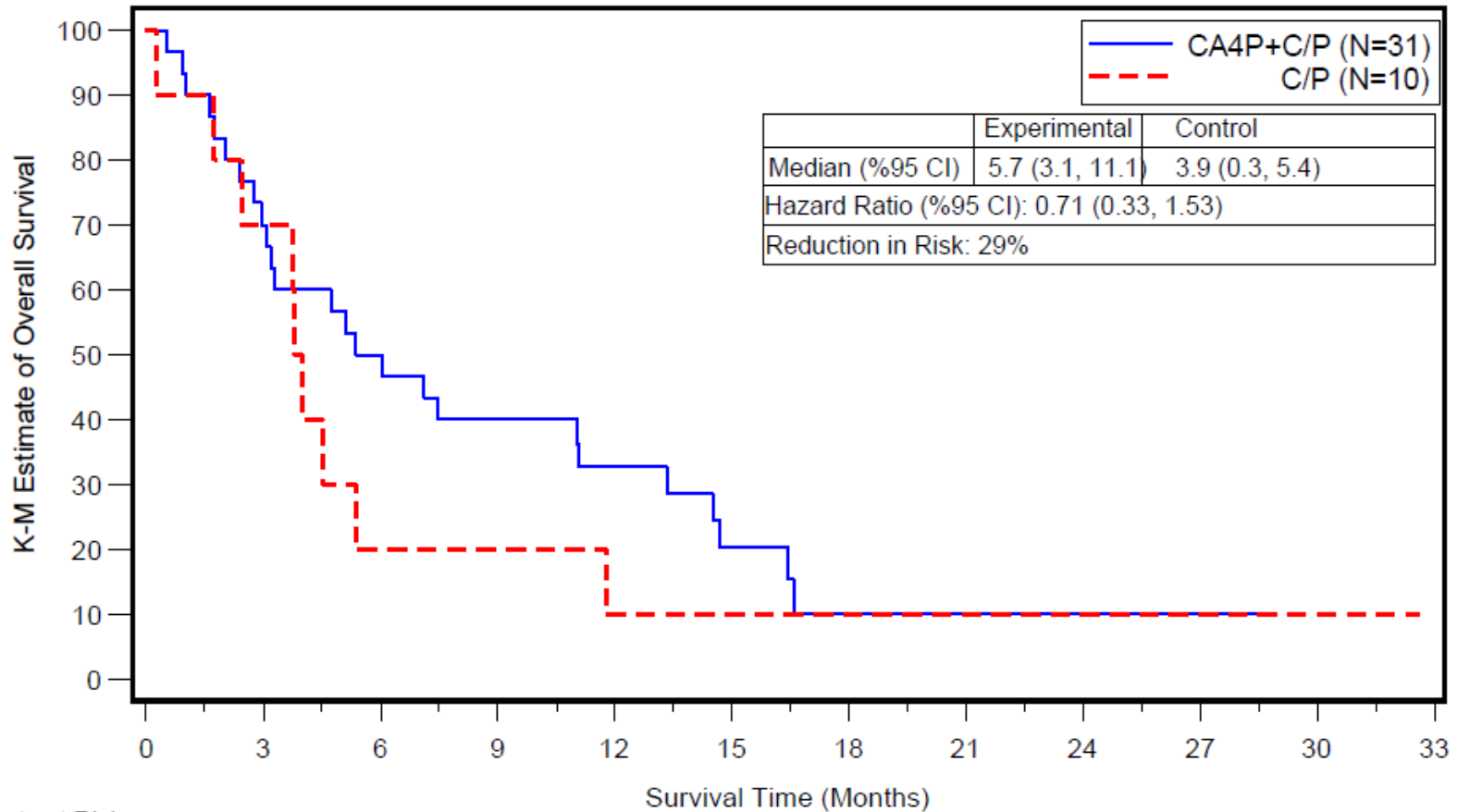
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# Overall Survival Tumor Size > 6 cm



Patients at Risk:

	0	3	6	9	12	15	18	21	24	27	30	33
Experimental N=31	31	21	15	12	9	5	2	2	2	1	-	-
Control N=10	10	7	2	2	1	1	1	1	1	1	1	1

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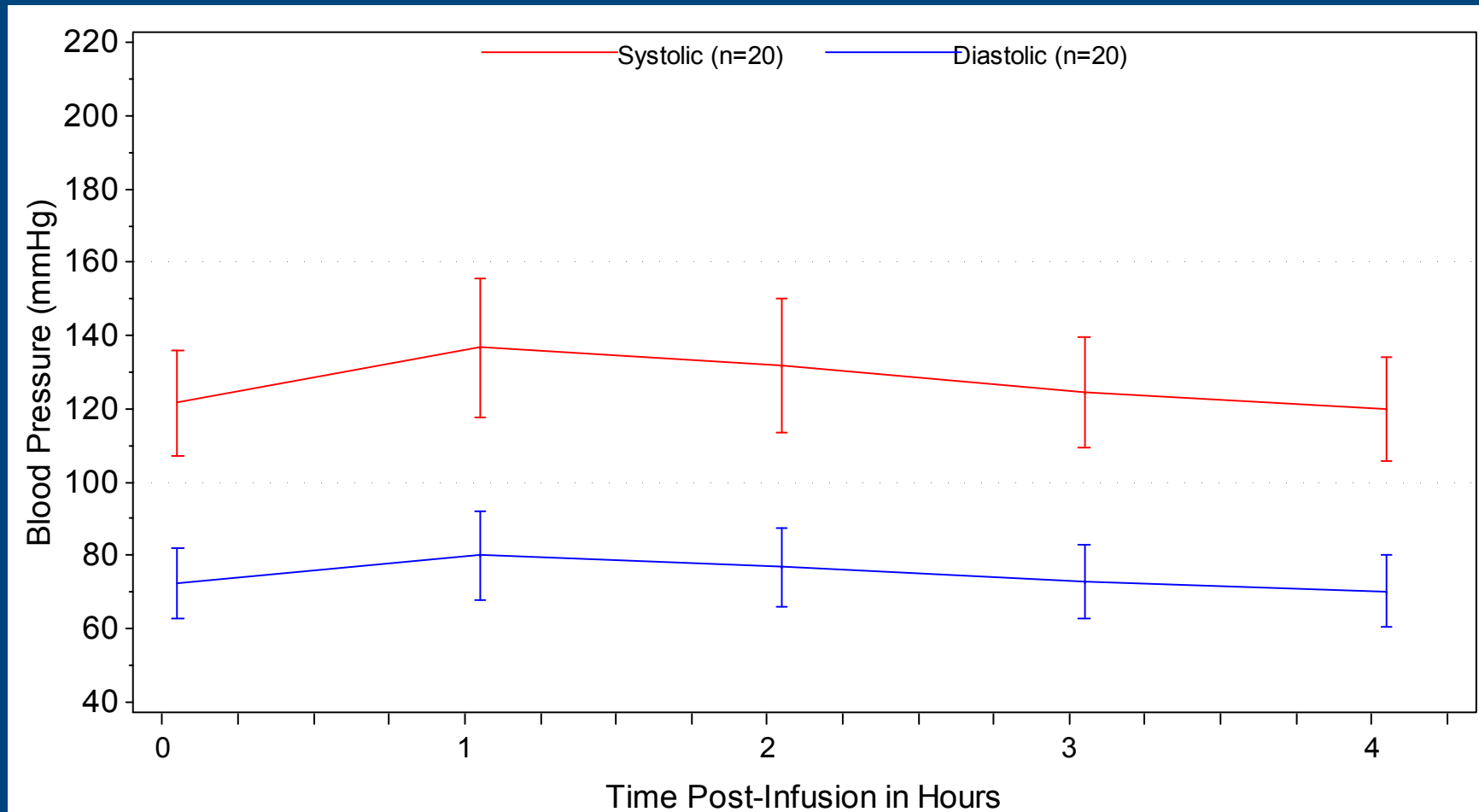








# Mean Blood Pressure After CA4P (Cycles 1-6\*)



\* Hypertension management guidelines followed including anti-hypertension prophylaxis

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includes only patients with pre-existing hypertension



# FACT Study Sites

- **Bulgaria:** A Tomova, V Tzekova, K Timcheva, M Koleva, F Marinov, A Foneva, O Mateva
- **India:** CS Bal, SM Karandikar, M Sengar, N Damle, B Shinde, H Patil, P Pai, A Shrivastava, S Shakya
- **Israel:** R BenYosef, O Bar-Am
- **Italy:** A Pinchera, R Elisei, H Koussis, L Licitra, L Pezzullo, M Maruzzo; Caponigro; E Molinaro, A Biagini, R Elisei, L Locati, R Granata, A Salzano, A Scola
- **Poland:** B Jarzab, J Krajewska, T Olczyk,
- **Republic of Belarus:** Y Demidchik, V Bariash, A Sarafanov, I Dzemiansava, N Aliferka, E Konovalchuk, M Frydman
- **Romania:** D Lungulescu, M Schenker
- **Russia:** G Manikhas, S Kutukova
- **Ukraine:** V Protsyk, O Halay, E Korobko, M Schmidt
- **United Kingdom:** C Nutting, N Reed, J Marshall, A Watson, R Nicole, M Ball, M Tanay, H Beveridge, G Howard-Jones
- **United States:** JA Sosa, A Gramza, M Heinrich, B Gitlitz, B Haugen, F Khuri, S Marur, F Ondrey, C Lu, S Remick, P Savvides, P Nichols, B Rose, D Quinn, J Pinski, I Shulman, M Said, J Klopper, J Candia, M Taylor, C Corless, K Schuff, D Shin, N Saba, C Weber, A Chen, W Grist, S Muller, S Logani, A Sabichi, G Blumenschein, E Kim, B Glisson, V Papadimitrakopoulou, M Stephen Kies, M Williams, S Sherman, A Tsao, R Zinner, D Stewart, K Pisters, S Lippman, D Karp, R Herbst, F Fosella, M Debnam, D Lenihan, W Westra, C Rudin, D Ball, A Forastiere, R Juergens, E Greeno, P Kumar, H Yee, T Rick, T Watson, L Reinhardt, P Gada, S Pambuccian, B Ducatman, J Remick, W Petros, T Hogan, M Auber, R Altaha, C Beall, S Kurian P Lavertu, J Bokar, M Cooney, J Wasman, A Dowlati, S Gettinger, K Haines, S Roman, H Deshpande, R Udelsman, F Israel

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