

CCTG SC.24/TROG 17.06:
A Randomized Phase II/III Study Comparing
24gy in 2 Stereotactic Body Radiotherapy
(SBRT) Fractions Versus 20gy In 5
Conventional Palliative Radiotherapy (CRT)
Fractions for Patients with Painful Spinal
Metastases

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Disclosures

- Employer: University of Toronto
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 - Advisory Board: Varian, VieCURE, ISRS, AOSPINE Tumour Knowledge forum co-chair
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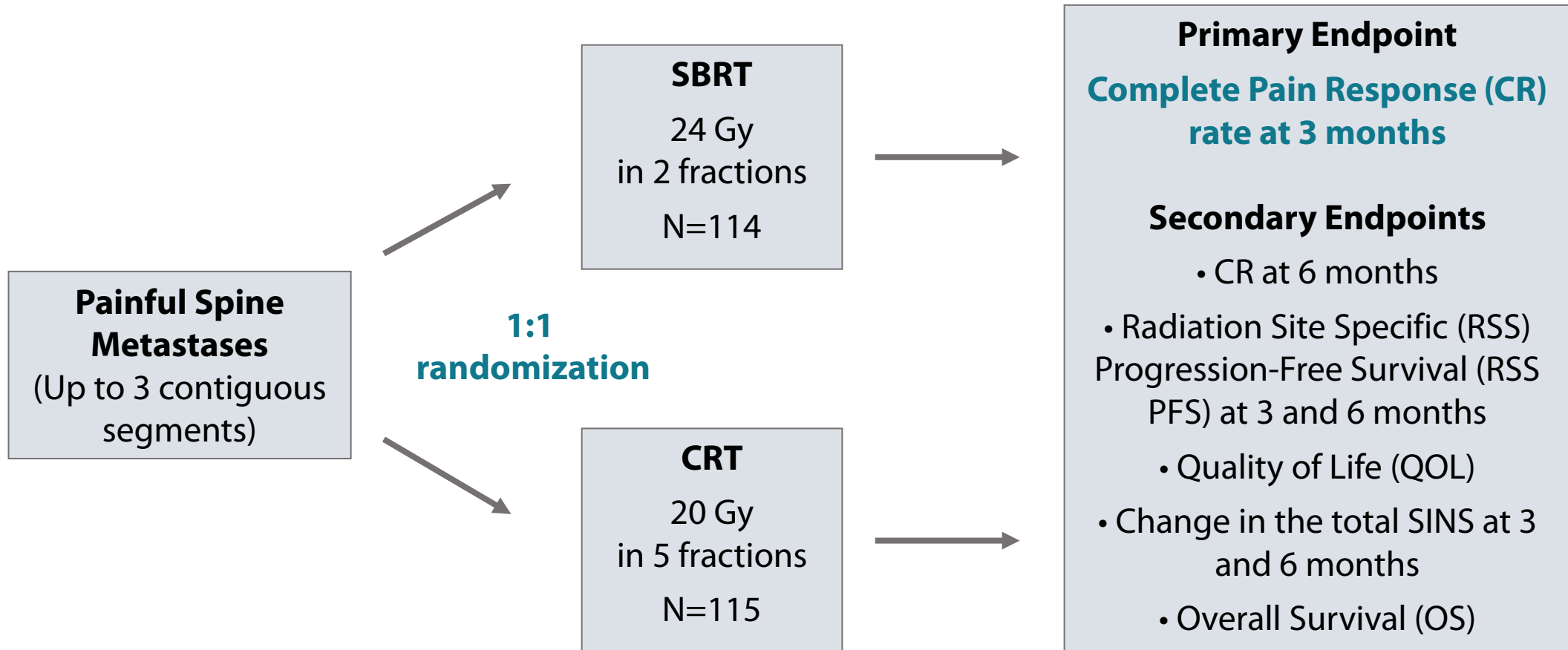
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Overview

- **Purpose:** For patients with painful spinal metastases, determine if complete pain response rate can be improved with spine SBRT vs. CRT
- SBRT fractionation scheme of 24 Gy in 2 fractions* compared with standard of care CRT regimen of 20 Gy in 5 fractions
- Phase 2/3 randomized controlled trial

Trial Design



Trial Participants

- Initial Phase 2 RCT converted to a Phase 3 RCT without interruption of accrual
- Accrual period: January 2016 – September 2019

	SBRT	CRT	Total
Total patients randomized	114	115	229
Did not receive study treatment	4	10	4
Not evaluable at 3 months	16	22	38
Intent to treat (ITT) analyses	114	115	229
Safety/QA Analyses (as-treated)	110	115	225

Results: Pain Response Rates

	3 Month Assessment		6 Month Assessment	
	SBRT (N=114)	CRT (N=115)	SBRT (N=114)	CRT (N=115)
Complete response	35%	14%	32%	16%
Partial response	18%	25%	9%	16%
Stable disease	24%	30%	23%	27%
Progressive disease	6%	12%	4%	7%
Indeterminant	18%	19%	32%	34%
Mean change in total SINS (SD)	-0.94 (1.69)	-0.49 (1.61)	-0.73 (1.86)	-0.74 (1.99)

Multivariable Analyses for CR at 3 and 6 months

Variable	3 Month Assessment			6 Month Assessment		
	Odds Ratio	95%CI	P Value	Odds Ratio	95%CI	P Value
SBRT	3.47	1.77-6.80	0.0003	2.45	1.28-4.71	0.007
CRT	1			1		
Age ≥ 65	1.58	0.82-3.06	0.17	0.65	0.34-1.25	0.20
Age < 65	1			1		
Male	1.33	0.54-3.26	0.54	1.39	0.56-3.45	0.48
Female	1			1		
ECOG 2	0.74	0.19-2.89	0.67	0.39	0.08-1.86	0.24
ECOG 0 or 1	1			1		
Pain Score at Baseline						
8 to 10	0.92	0.39-2.20	0.85	1.39	0.60-3.21	0.44
5 to 7	0.74	0.36-1.54	0.43	0.94	1.45-1.96	0.86
2 to 4	1			1		
Primary Cancer:						
GU (excluding RCC)	1.22	0.32-4.65	0.77	0.99	0.26-3.79	0.99
Lung	1.49	0.54-4.08	0.44	0.96	0.36-2.63	0.95
Other	0.58	0.09-3.77	0.57	0.74	0.14-3.86	0.72
Breast	1			1		
Total baseline SINS						
7 to 12	1.12	0.58-2.15	0.57	0.91	0.48-1.71	0.78
≤ 6	1			1		

Conclusions

- This is the first Phase 3 randomized trial to show that dose escalation with modern radiation therapy techniques improves pain outcomes for patients with spinal bone metastases
- Spine SBRT is superior to CRT and achieved a 21% absolute increase in the CR to pain at 3 months, which was durable at 6 months and statistically significant
- A regimen of 24 Gy in 2 SBRT fractions was safe, non-destabilizing and associated with better patient financial perception