

Stereotactic boost and Short-course Radiotherapy for p16-associated Oropharynx Cancer (SHORT-OPC): First Planned Interim Safety Analysis from a Randomized Phase II Trial

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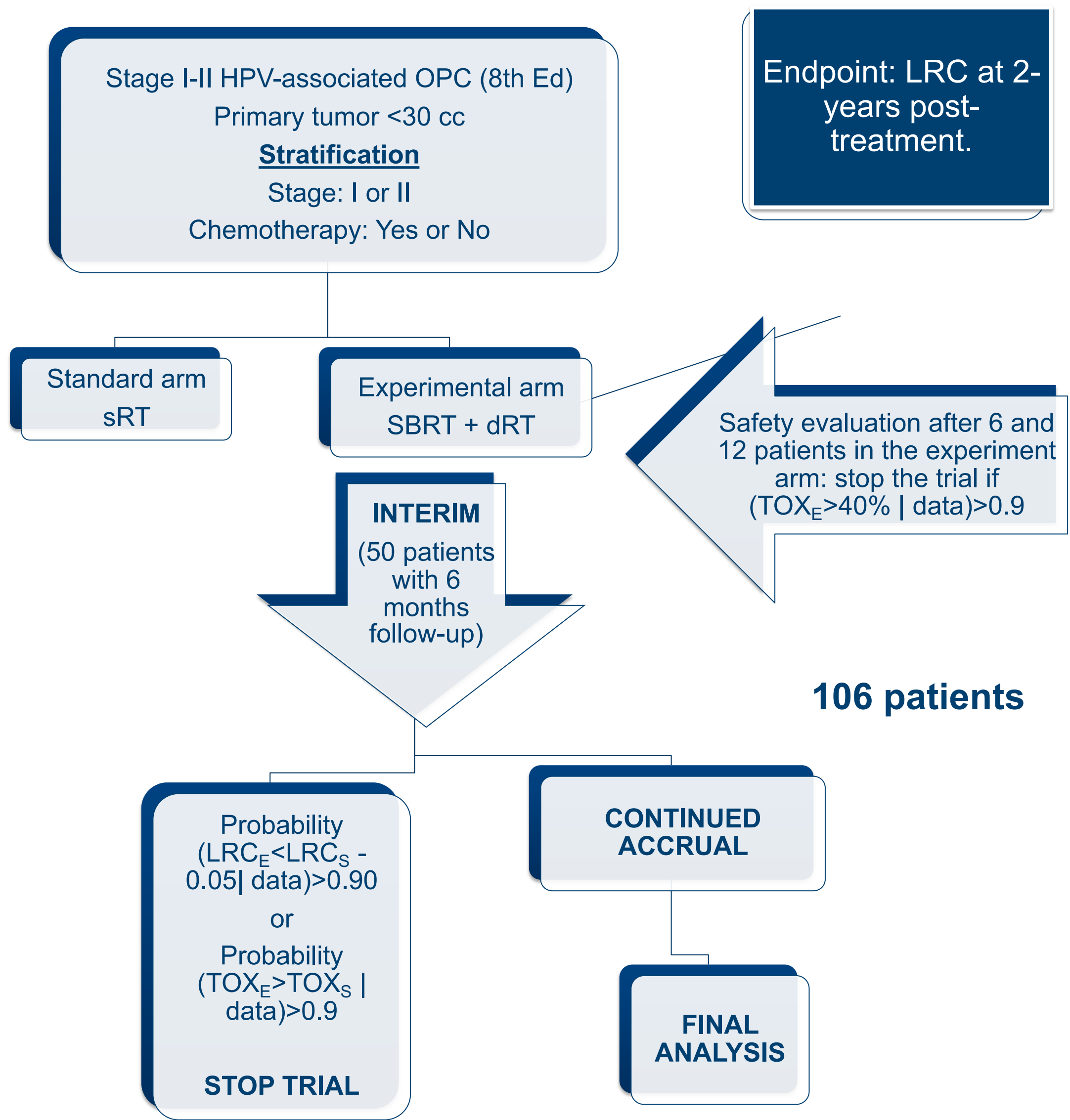
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Rationale

- The standard head & neck radiotherapy (RT) is cumbersome and associated with high toxicity.
- Stereotactic radiotherapy (SBRT) with image guidance is an opportunity to precisely target the gross tumor while safely reducing elective irradiation dose.
- Purpose: To assess the safety and efficacy of a short course RT for p16+ OPC, consisting in an SBRT boost to the gross tumor volume (GTV) followed by de-escalated elective RT.

Methods

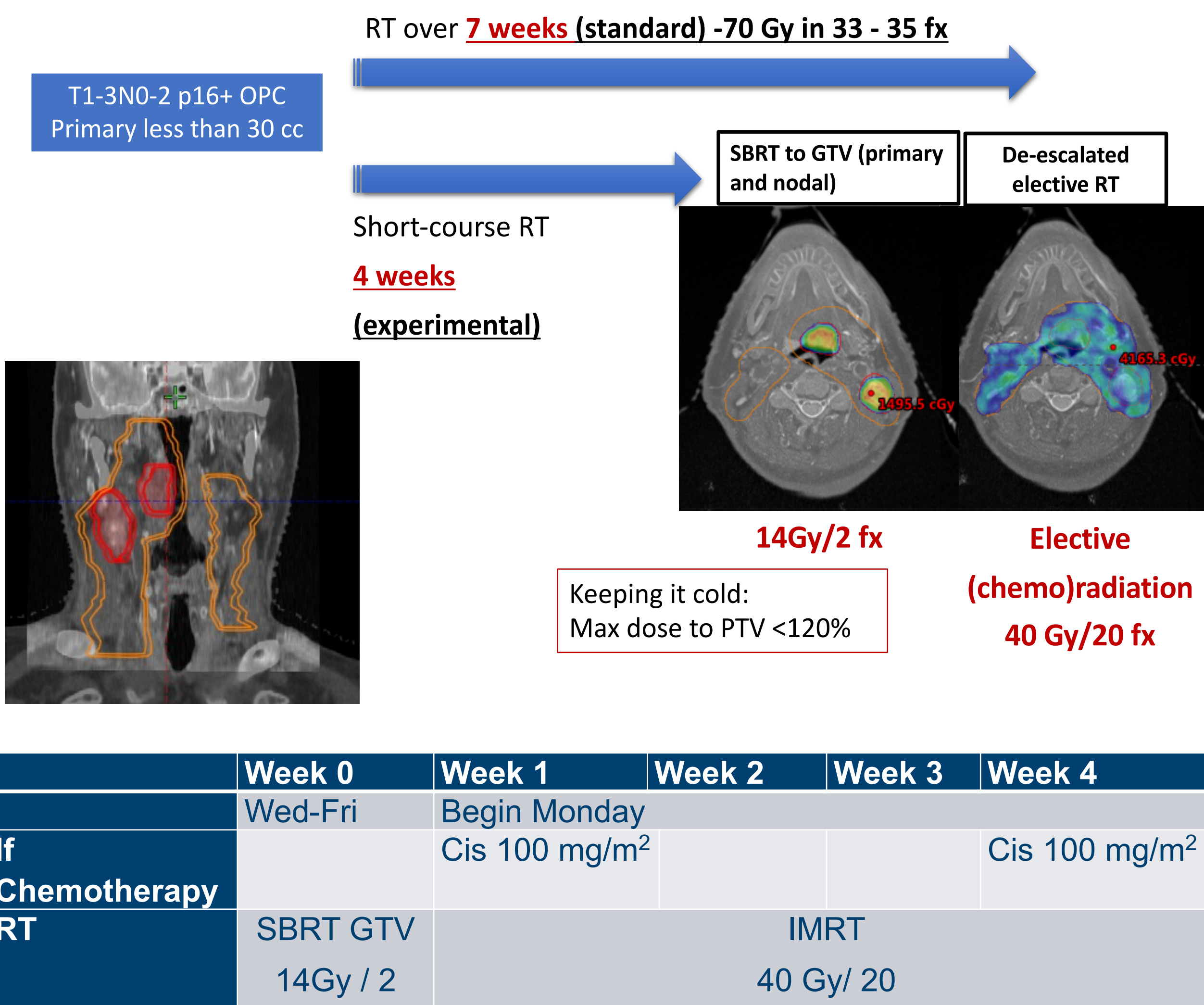
To compare locoregional control (LRC) from combined SBRT boost and de-escalated RT (dRT) versus standard 7-week course radiation (sRT).



Conclusion

This primary safety analysis showed that SBRT boost followed by a short course of de-escalated elective irradiation in p16+ OPC has limited early toxicity and meets criteria for study continuation.

Bayesian adaptive design : 2 planned safety and 1 futility analysis
Safety: grade ≥ 3 subacute toxicity >40% as a stopping criterion
(Subacute AE = between 60-180 days after RT)



Results

Age; y (M; range)	69 (49-84)
Stage T	
T1	29%
T2	71%
Stage N	
N0	10%
N1	85%
N2	1

- Data of 21 patients were analyzed.
- Follow-up: 11 months (range 2-18)
- 1 local recurrence in SOC arm (at 10 months) and no recurrence in experimental arm.

- 55% grade 3 acute AE in SOC arm vs. 30% in experimental arm.
- No grade 4 or 5; No grade ≥ 3 subacute or late

