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SELECTIVE INTERNAL RADIATION THERAPY OR SORAFENIB IN PATIENTS WITH LOCALLY ADVANCED HCC: SARAH AND SIRVENIB TRIALS

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SARAH AND SIRVENIB TRIALS

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- **SARAH:** Efficacy, tolerability and impact on quality of life of selective internal radiation therapy (with yttrium-90 resin microspheres) or sorafenib in patients with locally advanced hepatocellular carcinoma (HCC):
  - Presented at WCGIC 2017, Barcelona, LBA-001. Bouattour M et al.
- **SIRveNIB:** Randomized Phase III Trial of Selective Internal Radiation Therapy vs Sorafenib in Locally Advanced HCC:
  - Presented at ASCO 2017, Chicago, Abst 4002. Chow P et al.

TWO RANDOMIZED CONTROLLED PHASE III TRIALS

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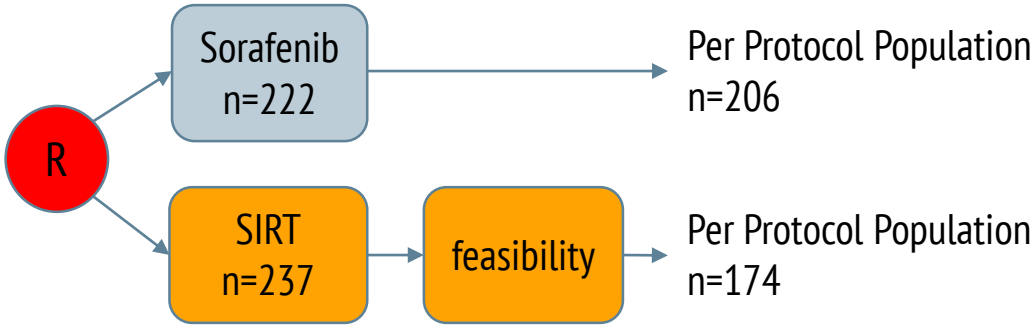
SARAH: French prospective open-label, phase 3, multi-center, randomized controlled trial

- Locally advanced HCC
- BCLC B or C
- No extrahepatic metastasis
- Child A or B ⩽7 points
- ECOG 0–1

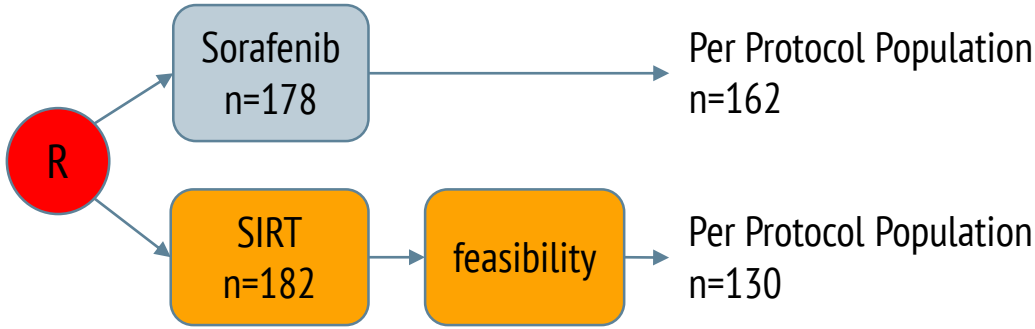
Stratify:
ECOG
Vascular invasion
Prior TACE
Institution



SIRveNIB: Asian prospective, open-label phase 3, multi-center randomized, controlled trial

- Locally advanced HCC
- BCLC B or C
- No extrahepatic metastasis
- Child A or B ⩽7 points
- ECOG 0–1

Stratify:
Site
Portal vein invasion



BASELINE CHARACTERISTICS

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	SARAH		SIRveNIB	
	SIRT (n=237)	Sorafenib (n=222)	SIRT (n=182)	Sorafenib (n=178)
Age, years; mean ± SD	65.8 ± 9.4	64.6 ± 9.4	59.5 ± 12.9	59.5 ± 12.9
Gender (male) %	89.5	91	81	85
Alcohol / HCV / NASH % HBV / HCV / HBV + HCV %	68.7 / 25.7 / 22.9	61.4 / 24.3 / 29.7	 51 / 14 / 2	 58 / 11 / 3
ECOG 0 %	61.2	62.6	74	79
Child-Pugh class/score: A / B7 %	82.7 / 16.5	84.2 / 15.8	90 / 10	88 /12
BCLC stage B / C %	27.8 / 68.4	27.5/ 67.1	55 /45	61 /39
TACE failure	44.7	42.3	–	–
Macrovascular invasion % Portal vein invasion %	62.9 34.3	57.7 32.2	– 31	– 30

CONCLUSION

- In the 2 trials, the primary endpoint was not reached
- Overall survival was not superior in the SIRT group compared to the sorafenib group

	SARAH				SIRveNIB			
	ITT population n=459		PP population n=380		ITT population n=360		PP population n=292	
	SIRT	Sorafenib	SIRT	Sorafenib	SIRT	Sorafenib	SIRT	Sorafenib
Median OS (mo)	8.00	9.9	9.9	9.9	8.8	10.0	11.3	10.2
HR (95% CI)	1.15 (0.85-1.25; p=0.76)		0.99 (0.79-1.24; p=0.92)		1.12 (0.88-1.02; p=0.36)		0.86 (0.66-1.13; p=0.27)	

ITT : Intention-To-Treat; PP: Per Protocol

SECONDARY ENDPOINTS

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Regarding secondary endpoints, SIRT seems to have some advantages

- Objective response rate was higher in SIRT group
- Progression in the liver as first site was significantly lower in the SIRT group
- However, extra hepatic progression was lower in sorafenib group
- Toxicity profile seems to favor SIRT group
- Quality of life assessed by Global Health Status subscore EORTC QLQ-C30 seems to favor SIRT group

IMPLICATIONS FOR CLINICAL PRACTICE

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- Sorafenib remains the standard of care in patients with locally advanced HCC
- SIRT failed to show superiority in terms of overall survival (OS) compared to sorafenib
- SIRT showed better local tumor control, tolerability and quality of life preservation compared to sorafenib
- SIRT could not be recommended in this setting but may be discussed within multidisciplinary teams as an alternative option in some selected patients with locally advanced HCC

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