Clinical Studies

SIR-Spheres® microspheres Clinical Programme

Where should SIR-Spheres® microspheres be **optimally** used in the **treatment paradigms** for unresectable liver tumours?

Over 40,000 patient treatments have been delivered using SIR-Spheres microspheres following regulatory approval for the treatment of liver tumours in Australia, Europe, the US and various countries in Asia. Sirtex continues to invest in and support an on-going programme of clinical investigations with the objective of:

- defining the optimal role for SIR-Spheres microspheres in the treatment of various unresectable liver tumours;
- further investigating the safety and effectiveness of SIR-Spheres microspheres in combination with new chemotherapy agents and regimens;
- investigating new indications for SIR-Spheres microspheres.

On-going Clinical Investigation Programme: Liver Tumours

Study Name	Sponsor	Setting	Design	Treatment Arm(s)	1º Endpoint	N	Location	Status
SIRFLOX[1]	Sirtex	1st-line CRC LM	RCT mc	FOLFOX (± bevacizumab) vs FOLFOX (± bevacizumab) + SIR-Spheres†	PFS	≥450	Global	On-going Recruited
FOXFIRE[2]	Collab.	1st-line CRC LM	RCT mc	OxMdG (FOLFOX) (± biologic) vs OxMdG (± biologic) + SIR-Spheres†	Survival	>1000	UK	Open
FOXFIRE-Global[3]	Sirtex	1st-line CRC LM	RCT mc	FOLFOX (± bevacizumab) vs FOLFOX (± bevacizumab) + SIR-Spheres†	Survival		Global	Open
SIR-STEP[4]	Collab.	1st-line CRC LM	RCT mc	1st-line chemo (3 months) → 5FU/LV vs 5FU/LV + SIR-Spheres†	TTP1	162	Europe	Open
*in*SIRT/ UCSD 071960[5]	IRT	2nd-line CRC LM	sa, sc	SIR-Spheres† > 2nd-line chemotherapy	PFS	34	USA	Open
SIR*KRAS*	Collab.	2nd-line *KRAS*^{mut} CRC LM	RCT mc	2nd-line chemotherapy vs 2nd-line chemotherapy + SIR-Spheres†	PFS	134	Italy	Open
Fox Chase 04043[6]	IRT	CRC LM	sa, sc	capecitabine + SIR-Spheres†	Safety/MTD	22–37	USA	Open
SIR*ve*NIB[7]	Collab.	HCC	RCT mc	sorafenib vs SIR-Spheres†	Survival	360	Asia-Pacific	Open
SARAH[8]	Collab.	HCC	RCT mc	sorafenib vs SIR-Spheres†	Survival	400	France	Open
SORAMIC[9]	IRT	HCC	RCT mc	sorafenib vs SIR-Spheres† > sorafenib	Survival	375	Europe	Open
TrYPHon[10]	IRT	HCC; prior to resection or RFA	sa, mc	SIR-Spheres†	Safety	50	Belgium	Open
Emory University WCI2031-11[11]	IRT	mNET LM	sa, sc	pasireotide + everolimus + SIR-Spheres†	Safety/MTD	49	USA	Open
SIRMITOC	IRT	refractory breast LM	sa, sc	SIR-Spheres† > mitomycin C	Safety/efficacy	15	Belgium	Open
CHOLANGIOSIR[12]	IRT	2nd-line ICC	sa, mc	SIR-Spheres†	PFS	20	France	Open
Johannes Gutenberg University[13]	IRT	ICC	RCT sc	SIR-Spheres† vs TACE (DEBDOX)	PFS	24	Germany	Open
SIRUM[14]	IRT	1st/2nd-line uveal melanoma LM	sa, sc	SIR-Spheres†	Clinical benefit/ safety	48	USA	Open
Vaudois University[15]	IRT	uveal melanoma LM	sa, sc	SIR-Spheres† > sorafenib or Sorafenib > SIR-Spheres†	Safety	24	Switzerland	Open

Key: 1º: primary; CRC: colorectal cancer; LM: liver metastases; < randomised controlled trial; mc: multi-centre; †: SIR-Spheres microspheres; PFS: progression-free survival; Global: Asia-Pacific, Europe and USA; Collab.: collaborative group study (FOXFIRE: University of Oxford/UK National Cancer Research Institute; SIR-STEP: Belgian Group of Digestive Oncology; SIR*KRAS*: SITILO-Italian Society of Integrated Locoregional Therapies in Oncology; SIR*ve*NIB: Singapore Clinical Research Institute/National Medical Research Council (NMRC), Singapore; SARAH: Assistance Publique – Hôpitaux de Paris); biologic: biologic agent (e.g. bevacizumab; cetuximab); TTP: time to progression; IRT: investigator-initiated research trial; sa: single arm; sc: single centre; MTD: maximum tolerated dose; HCC: hepatocellular carcinoma; ICC: intra-hepatic cholangiocarcinoma

Continued overleaf

Study Name	Sponsor	Setting	Design	Treatment Arm(s)	1º Endpoint	N	Location	Status
Treatment Planning								
EXPLOSIVE[16]	IRT	CRC LM	RCT sc	^{99m}Tc-B20 HSA microspheres < ^{99m}Tc-MAA	Predictive value	24	Germany	On-going but not recruiting

Key: 1º: primary; IRT: investigator-initiated research trial; CRC: colorectal cancer; LM: liver metastases; < randomised controlled trial; sc: single centre; Tc: Technetium; HSA: human serum albumin; MAA: macroaggregated albumin

On-going Clinical Investigation Programme: Primary Renal Cell Carcinoma

Study Name	Sponsor	Setting	Design	Treatment Arm(s)	1º Endpoint	N	Location	Status
RESIRT[17]	Sirtex	advanced 1º RCC	First in human study	SIR-Spheres†	Safety/MTD	15–24	Australia	Open

Key: 1º: primary; RCC: renal cell carcinoma; †: SIR-Spheres microspheres; MTD: maximum tolerated dose

SIR-Spheres microspheres are approved in Australia, the European Union (CE Mark) and several other countries for the treatment of patients with advanced non-operable liver tumours.

References

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2. www.controlled-trials.com/isrctn/pf/83867919
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