Clinical Study in intrahepatic cholangiocarcinoma

Currently Enrolling Patients

The SIRCCA Study

SIR-Spheres® Y-90 resin microspheres preceding CIS-GEM *versus* CIS-GEM alone in patients with unresectable intrahepatic cholangiocarcinoma

A prospective, multicentre, randomised controlled study evaluating SIR-Spheres® Y-90 resin microspheres preceding standard-of-care CIS-GEM chemotherapy *vs.* CIS-GEM alone as first-line treatment of patients with unresectable intrahepatic CholangioCArcinoma (SIRCCA)

Purpose: To assess the efficacy and safety of adding targeted radiation, in the form of SIR-Spheres Y-90 resin microspheres preceding standard-of-care cisplatin-gemcitabine (CIS-GEM) systemic chemotherapy compared to CIS-GEM alone as first-line treatment of patients with unresectable intrahepatic cholangiocarcinoma (ICC).

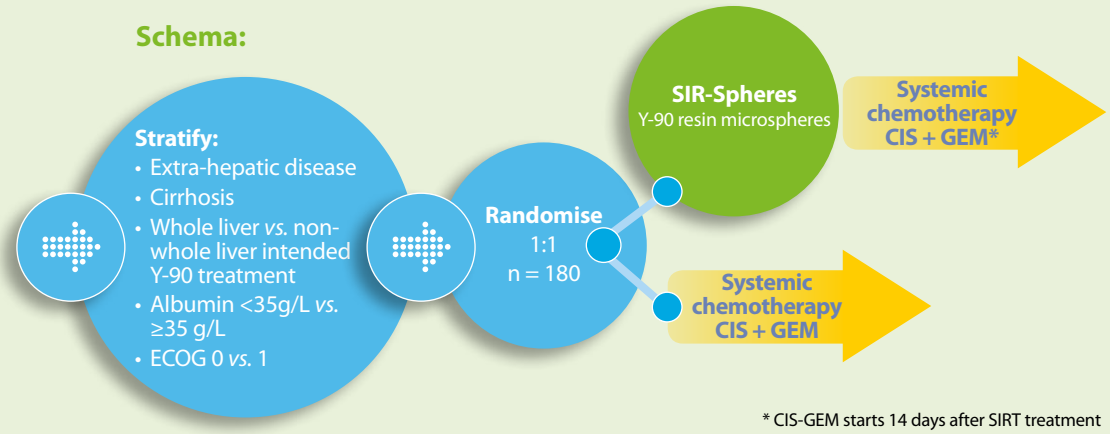
Study Design: Prospective, open label, multicentre and multi-national RCT

The SIRCCA Study

Key eligibility criteria:

- Unresectable ICC
- No prior chemotherapy
- ECOG PS 0–1
- Suitable for SIRT and systemic chemotherapy
- No or limited extra-hepatic disease

Schema:



* CIS-GEM starts 14 days after SIRT treatment

ClinicalTrials.gov Identifier:	• NCT02807181
Sponsor:	• Sirtex Technology Pty Ltd
Investigators:	• Jordi Bruix, Hospital Clinic, Barcelona, Spain • Harpreet Wasan, Imperial College Healthcare Hammersmith Hospital, London, UK
Study Population:	• n = 180
Primary Endpoint:	• Survival rate at 18 months

Secondary Endpoints:	• Liver-specific PFS • PFS at any site • ORR by RECIST 1.1 and refined RECIST in the liver • ORR by RECIST 1.1 and refined RECIST at any site • Overall Survival • Liver surgical resection and ablation rate • Safety (CTCAE v4.03) and tolerability • Quality of Life
Key Inclusion Criteria:	• Histologically or cytologically confirmed unresectable and/or non-ablatable ICC • Liver-only or liver-predominant ICC • Chemotherapy naïve • ECOG performance status 0 or 1 • Adequate haematological, renal and liver function
Key Exclusion Criteria:	• Patients with only non-measurable lesions in the liver according to RECIST criteria • Incomplete recovery from previous liver surgery • Biliary stent *in situ* • Ascites, even if controlled • Main trunk Portal Vein Thrombosis (PVT) • Mixed HCC-ICC disease • Suspicion of any bone or CNS metastasis/metastases on clinical or imaging examination • Prior internal or external radiation delivered to the liver
Participating Regions:	• Australia • Europe (Belgium, France, Germany, Italy, Spain, The Netherlands, Ireland and UK) • USA
For More Information Contact:	• info-au@sirtex.com • info-emea@sirtex.com • info-us@sirtex.com

SIR-Spheres Y-90 microspheres are approved for use in Argentina, Australia, Brazil, Canada, the European Union (CE Mark), Switzerland, Turkey, and several countries in Asia for the treatment of unresectable liver tumours.
In the US, SIR-Spheres Y-90 resin microspheres have a Pre-Market Approval (PMA) from the FDA and are indicated for the treatment of unresectable metastatic liver tumors from primary colorectal cancer with adjuvant intra-hepatic artery chemotherapy (IHAC) of FUDR (Floxuridine).

This information is intended for clinical investigators and other interested physicians who may wish to enroll or refer patients into this study.
Not for distribution to potential or currently enrolled study subjects.

SIR-Spheres®
Y-90 resin microspheres

SIRTeX

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