

SORAMIC STUDY

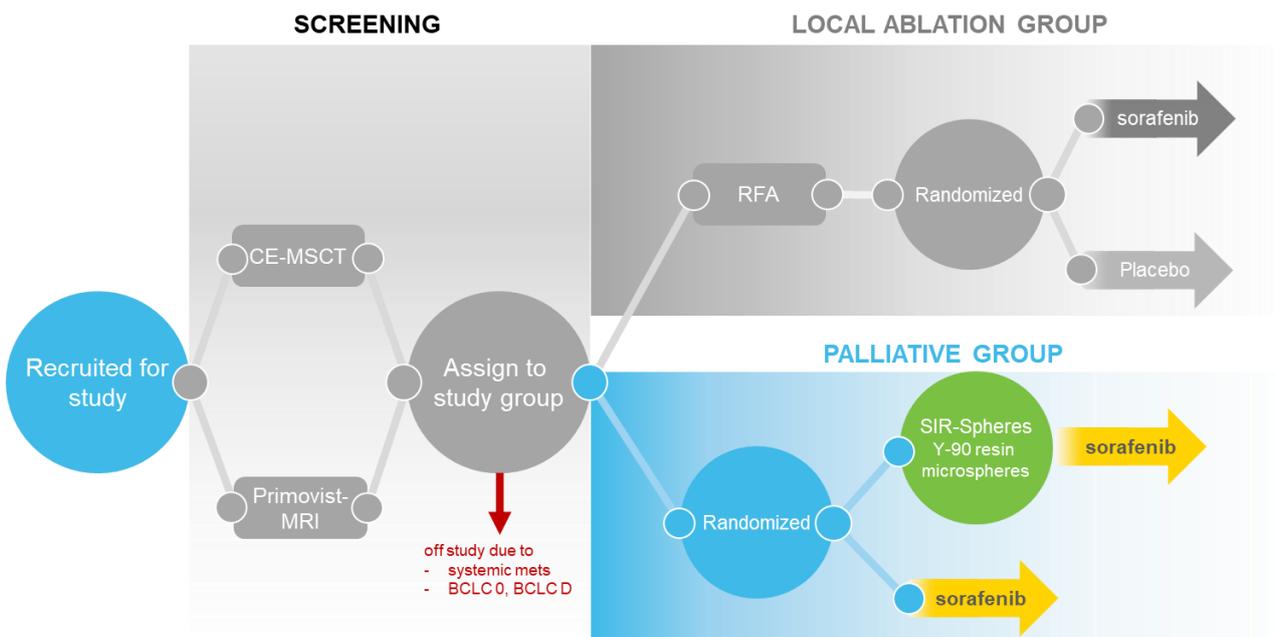
What is the SORAMIC study?

The goal of the Pan-European SORAMIC study was to assess in a “real world setting” the effects of two treatment options for patients with hepatocellular carcinoma (HCC). In patients with early stage HCC (the “local ablation group”), the systemic agent, sorafenib, was investigated in a blinded fashion as adjuvant therapy after radiofrequency ablation (RFA) of their liver tumours versus placebo. In patients with advanced HCC (the “palliative group”), Selective Internal Radiation Therapy (SIRT) was used to treat liver tumours locally, followed by daily systemic treatment with sorafenib and investigated versus the standard treatment of systemic sorafenib alone.

Sorafenib is the standard systemic therapy for patients with unresectable locally advanced HCC and well preserved liver function. It was first approved in 2007, based on a pivotal study that demonstrated an increase in median survival from 7.9 months to 10.7 months in patients with advanced disease.¹

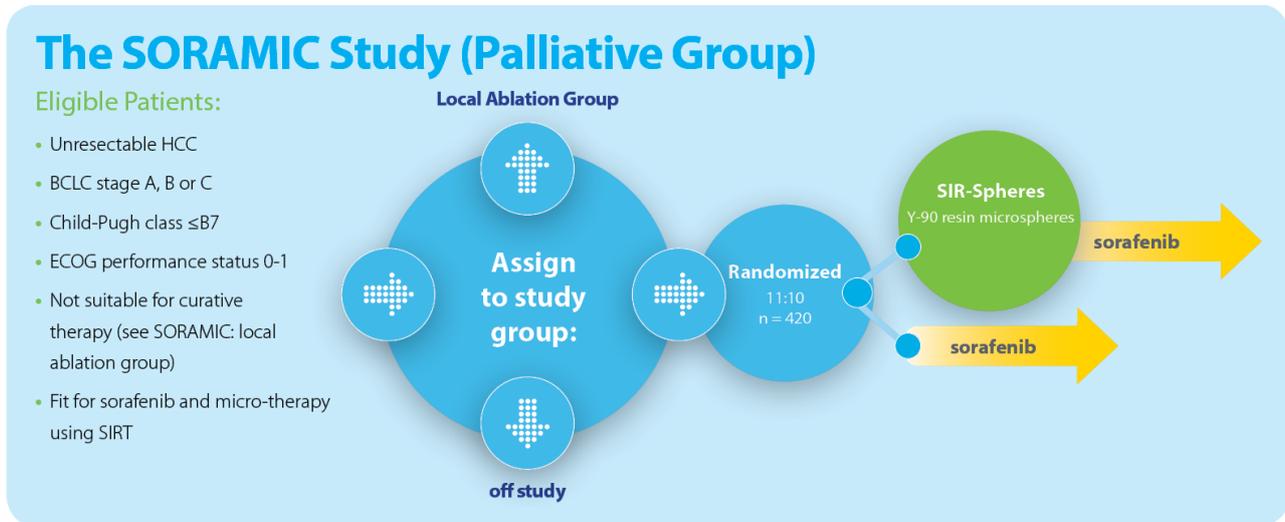
The palliative cohort of the SORAMIC study is the first large head-to-head Randomised Controlled Trial (RCT) to compare the efficacy and safety of combining sorafenib and SIR-Spheres® Y-90 resin microspheres versus sorafenib alone for the first-line treatment of patients with advanced HCC.

The study started in December 2010 and completed enrolment of 420 patients in February 2016.



What was the study design?

SORAMIC is a Europe-wide randomized, multi-centre study.



Which outcomes were measured in the study?

The primary endpoint of the “Palliative Group” of the SORAMIC study is Overall Survival (OS) and the primary objective is to demonstrate a significant increase in OS with sorafenib + SIR-Spheres Y-90 resin microspheres vs sorafenib alone.

The secondary endpoints are:

- Health-Related Quality of Life
- Safety and toxicity
- OS separately for patients with and without portal vein thrombosis

An interim safety analysis of the first 40 patients indicated that SIR-Spheres Y-90 resin microspheres followed by escalation of the sorafenib dose was not associated with increased toxicity compared to sorafenib alone in patients with advanced HCC. Moreover, patients receiving SIR-Spheres Y-90 resin microspheres benefited from the same intensity and duration of sorafenib treatment as the control arm.²

How many patients participated in SORAMIC?

With 420 patients recruited in the palliative cohort, SORAMIC is the largest study to investigate the effect of the combination of SIR-Spheres Y-90 resin microspheres and sorafenib as a first-line treatment of advanced HCC.

Where was SORAMIC conducted?

The SORAMIC study was conducted at 30 sites in 12 European countries including Austria, Belgium, Germany, France, Italy, The Netherlands, Poland, Slovenia, Spain, Switzerland, Turkey and United Kingdom. The Principal Investigators of SORAMIC are Prof Jens Ricke, professor of radiology, and Prof Peter Malfertheiner, professor of gastro-hepato oncology, at the University of Magdeburg, Germany,

Which types of patients were included in the study?

The palliative cohort of SORAMIC included patients with advanced HCC, who were not eligible for the local ablation study group. All patients in this group received sorafenib.

The following study inclusion criteria applied to the palliative group:

- Liver-dominant or liver-only unresectable HCC
- BCLC Stage A, B, or C
- Child-Pugh class A or B ≤7 points
- ECOG performance status 0-1
- Adequate haematological function
- Not eligible for TACE
- Not eligible for the curative group (exclusion criteria in this group were extrahepatic disease and invasion of the portal vein main stem, or invasion of the right / left portal vein)

Which types of patients were excluded from the study?

Patients were excluded if, for example, they had an ECOG performance status >2; pulmonary metastases; uncontrolled ascites; a whole-liver tumour burden > 70%; history of haemorrhage / bleeding events of grade ≥ 3; any previous external beam radiation therapy to the liver; hepato-pulmonary shunt leading to an anticipated lung dose > 30 Gy; previous therapy with monoclonal antibodies. Patients were also excluded if they were pregnant or breast feeding at the time of the study.

When will the results be available?

Data from the palliative cohort of the SORAMIC study are expected to be presented at a major medical congress in 2018.



SIR-Spheres Y-90 resin microspheres are tiny radioactive resin beads that emit radiation and possess unique physical characteristics and biological effects.³ They are only about one third the width of a human hair and have about the same specific gravity as a red blood cell. This enables the microspheres to flow easily in the blood and become lodged in the small blood vessels around the liver tumour where they destroy it while sparing the surrounding healthy tissue.

For more information please visit:

www.soramic.com/

www.sirtex.com/eu/clinicians/hcc-clinical-studies/soramic/

www.sirtex.com

1. Llovet JM *et al.* *N Engl J Med* 2008; **359**: 378–90.
2. Ricke J *et al.* *Liver Int* 2015; **35**: 620–626.
3. Walrand S *et al.* *J Nucl Med* 2014; **55**: 1317–22.