The FAST Trial

SIR-Spheres® + FOLFOX + Avastin® in Patients with Unresectable Liver Metastases from Colorectal Cancer

Pilot trial evaluating the safety and effectiveness of SIR-Spheres microspheres in combination with FOLFOX6m chemotherapy plus the biologic therapy bevacizumab (Avastin), for the first-line treatment of patients with unresectable liver-only or liver-predominant colorectal cancer metastases.

Purpose: To assess the safety and effectiveness of adding targeted radiation, in the form of SIR-Spheres microspheres, to a standard systemic chemotherapy regimen of FOLFOX6m plus bevacizumab (Avastin) as first-line therapy in patients with unresectable liver metastases from primary colorectal adenocarcinoma.

Trial Design: Prospective open-label, multi-center pilot trial.

Eligible Patients:
- Unresectable liver-only or liver-predominant colorectal cancer metastases
- No prior chemotherapy for advanced disease
- Fit for combination therapy and selective internal radiation therapy (SIRT)

Schema:
- SIR-Spheres microspheres implanted day 3–4 of Cycle 1
- bevacizumab commences Cycle 3
- oxaliplatin administered at 60 mg/m² for Cycles 1–3

ClinicalTrials.gov Identifier: NCT00735241

Trial Population:
- n = 30

Primary Endpoint:
- Toxicity and safety

Secondary Endpoints:
- Progression free survival at any site
- Progression free survival in the liver
- Overall survival
- Tumor response rate (liver ± any site)
- Hepatic and extra-hepatic recurrence rate
- Health-Related Quality of Life
- Rate of down-staging to surgical resection or ablative therapy

This information concerns a use that has not been approved or cleared by the Food and Drug Administration (FDA). This use is approved in the European Union, Australia and several other countries.

This trial is being conducted in the USA under an Investigational Device Exemption (IDE) issued by the FDA. SIR-Spheres microspheres are indicated in the USA for the treatment of unresectable metastatic liver tumors from primary colorectal cancer with adjuvant intra-hepatic artery chemotherapy using floxuridine.

SIR-Spheres microspheres are approved in Australia, the European Union (CE Mark) and several other countries for the treatment of unresectable liver tumors.
Key Inclusion Criteria:

- Histologically confirmed adenocarcinoma of the colon or rectum
- Unequivocal and measurable CT evidence of liver metastases which are not treatable by surgical resection or local ablation with curative intent
- Limited extra-hepatic metastases in the lungs, bones and/or abdominal or hilar lymph nodes are permitted
- Adequate haematological, renal and hepatic function
- ECOG Performance Status 0 – 1
- Life expectancy >3 months without any active treatment

Key Exclusion Criteria:

- Evidence of ascites, cirrhosis, portal hypertension, main portal venous tumour involvement or thrombosis
- Any extra-hepatic metastases other than metastases in the lungs and/or bones and/or abdominal or hilar lymph nodes. Central nervous system (CNS) metastases are not allowed
- Prior chemotherapy for metastatic colorectal cancer (adjuvant chemotherapy for colorectal cancer is permitted provided that it was completed ≥6 months before documentation of metastatic disease)
- Other active malignancy or prior chemotherapy for any other malignancy
- Previous radiotherapy delivered to the upper abdomen
- Peripheral neuropathy > grade 1 (NCI-CTCv3)
- Pregnant or breast feeding

Participating Countries:

- USA

For More Information Contact:

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Local Treating Center:

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

Reference: