

Clinical Study Synopsis: CIRSE Emprint Microwave Ablation Registry (CIEMAR)

1. CIRSE Emprint Microwave Ablation Registry (CIEMAR)

In the attempt to further the evidence on interventional radiological treatments CIRSE has started sponsoring observational studies (registries) in the field of minimally-invasive, image-guided therapies. The CIRSE Emprint Microwave Ablation Registry (CIEMAR) aims to collect real-life data on the microwave ablation (MWA) of colorectal liver metastatic disease using the Emprint Microwave Ablation System.

2. Background

Colorectal adenocarcinoma is the third most diagnosed type of cancer and about 50% of the patients develop liver metastases over the course of the disease. Only 10-15% of patients are suitable for surgical resection of liver metastases and alternative treatments need to be considered. Microwave ablation provides a minimally-invasive treatment that has proven its efficacy in multiple randomised trials. However, the clinical acceptance of the therapy is still limited. Many patients that could benefit from MWA do not have access to the therapy. One of the main causes of this being the lack of data from large multi-centric, cross-border cohorts necessary to convince referrers and payers. The CIRSE Emprint Microwave Ablation Registry (CIEMAR) intends to close this gap and collect data on 1000 CRLM patients from at least 8 European nations.

3. Governance

CIEMAR is governed by a multidisciplinary, pan-European Steering Committee which is co-chaired by the coordinating investigators Prof. Philippe Pereira (Interventional Radiologist, SLK-Kliniken GmbH Heilbronn, Germany) and Prof. Thierry de Baère (Interventional Radiologist, Institut de Cancérologie Gustave Roussy, France). The study is funded by a contractually agreed research grant provided by Medtronic.

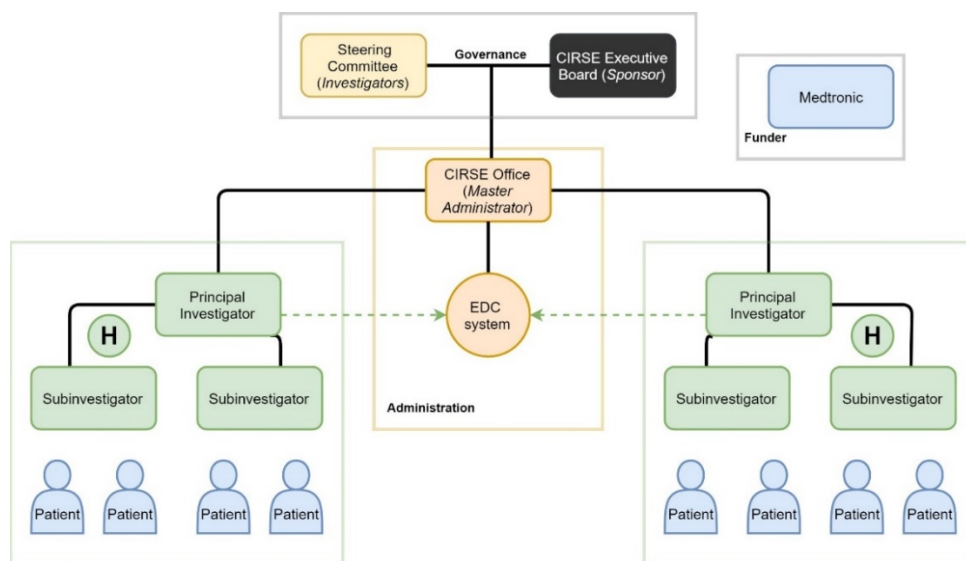


Figure 1: CIEMAR Governance Structure

4. Study design

CIEMAR is a European-wide prospective observational study that will assess treatment outcomes of CRLM patients treated with the Emprint MWA device. Participating centres are selected based on the experience with MWA using the Emprint device and will receive reimbursement of 500€ per patient.

The study is planned to start data collection in January 2020 and enrol patients for two years. Patients are planned to be followed up to three years. The projected closing date for data collection is January 2025.

Component	Description
Project timescale	5 years (data collection from January 2020 - January 2025)
Study assessment schedule	Baseline: up to 1 month before treatment Treatment Follow-up 1: Treatment + 1 month Follow-up 2: Treatment + 3 months Follow-up 3: Treatment + 6 months Follow-up 4: Treatment + 9 months Follow-up 5: Treatment + 12 months Follow-up 6 – 13: Every 6 months thereafter until end/exit of study OR death
Primary Objective	To assess the effectiveness of microwave ablation performed with the EMPRINT device in controlling colorectal metastatic tumours in the liver.
Primary endpoint	Local tumour control at 12 months after treatment on a per lesion basis
Secondary objectives	Evaluate Safety and Toxicity, Survival, Efficacy parameters, Quality of Life and Economic aspects of MWA for CRLM.
Secondary endpoints	<ul style="list-style-type: none"> • Overall survival • Progression free survival • Hepatic progression free survival • Time to untreated progression by ablation • Systemic cancer therapy vacation • Time to disease control by ablation • Secondary resection or ablation • Quality of Life • Economic aspects
Study design	Prospective, single-arm, observational study (registry)
Study population	All patients in participating centres receiving microwave ablation for colorectal liver metastases as their standard of care and are within the inclusion criteria should be included in CIEMAR.
Procedures	Open, laparoscopic or percutaneous ablation of colorectal liver metastases using the Emprint Microwave Ablation System.
Patient target	Target population of 1000 patients was chosen.
Reimbursement	500€ per patient
Patient population	Patients with colorectal adenocarcinoma with liver-only or dominant liver metastases treated with the Emprint Microwave Ablation System.
Statistical methods	CIEMAR is a single arm study that will use mainly descriptive statistics to report endpoints. A separate statistical analysis plan will be drafted, and finalised based on an interim analysis.