

CIRSE Registry for LifePearl Microspheres (CIREL) Summary

1. Background

Transarterial chemoembolisation (TACE) using drug-eluting beads loaded with irinotecan is a minimally invasive treatment for liver metastases. Since liver metastases receive most of their blood supply via the arterial route, arterial infusion of these metastases with drug-eluting beads preloaded with irinotecan may offer a chance of local therapy. Previous studies have shown promising results with regards to effectiveness and safety, but further understanding of the real-life clinical application of TACE with LifePearl Microspheres is needed. Therefore, the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) initiated the CIRSE Registry for LifePearl Microspheres (CIREL).

2. Steering Committee

CIREL 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, Heilbronn, Germany) and Prof. Julien Taieb (Medical Oncologist, Georges Pompidou European Hospital, France).

3. Study design and objectives

CIREL is a European-wide prospective observational registry, collecting clinical data that enables the evaluation of treatment modalities and achieved clinical results of TACE with LifePearl Microspheres throughout Europe.

The primary objective of the research project is to better understand the real-life clinical application of TACE with LifePearl Microspheres by prospectively collecting data on treatment modalities to ultimately determine at which stage of the disease the treatment is being conducted. Secondary objectives of CIREL are to assess the observed treatment outcomes in terms of safety and efficacy as well as trying to explore predictive response factors.

Imaging measurements included in CIREL may assist in establishing the primary endpoint and are essential for determining the secondary efficacy endpoints. To minimise bias and variability of medical image interpretations, CIREL includes an independent central review of three medical images, taken at key points in the treatment timeline.

To better understand the palliative aspect of the treatment, the change in patient-reported quality of life is measured by means of EORTC's validated quality of life questionnaire QLQ-C30. The questionnaire is based on voluntary participation of the patient and may be rejected at any time.

All therapy and follow-up parameters are detected by means of an electronic CRF (Case Report Form). The encoded patient data is collected centrally in an Electronic Data Capture system hosted by OpenClinica and stored on their secured servers in the UK.

4. Patient population

CIREL will prospectively collect data on patients with colorectal adenocarcinoma with liver-only or dominant liver metastases that are being treated with TACE with LifePearl Microspheres as part of their standard treatment. In no way will the participation of the patient in the registry impact their treatment

plan or influence the quality of the treatment. Patients need to be adequately informed about the registry and are required to sign an informed consent or data release form (depending on local regulation) before data collection can begin.

5. Hospital Selection Criteria

Only centres who performed 40 or more TACE treatments in their entire case history or 10 or more TACE treatments in the last 12 months can participate in the CIREL registry. In both cases, it is also required that a minimum of one treatment with LP-IRI has been performed.

6. Study end

The study has no fixed end date and will be closed at the discretion of the CIREL Steering Committee only when sufficient data has been collected to make clinically relevant statements. It is assumed that the registry will run for a minimum of four years.