

Treatment with SIR-Spheres® in non resectable liver tumours

Dear patient

Below you will find information regarding the planned investigation

1. Introduction

SIR-Spheres® are indicated for the treatment of malignant liver tumours of primary or secondary origin, which are not suitable for complete surgical resection. Liver cancer is considered as resectable if, according to an experienced liver or bile surgeon, all macroscopic visible tumour components can be removed and there still will remain enough healthy liver tissue in the body to maintain the necessary lifesaving function. The therapy with SIR-Spheres® is authorized for this indication in the European Union.

SIR-Spheres® are approximately 30 micrometers in diameter, are biocompatible microspheres (beads), which contain the radioactive substance Yttrium-90. SIR-Spheres® are intended for implantation into malignant liver tumours for the selective delivery of high doses of ionizing radiation to the tumour. This is achieved by introducing SIR-Spheres® into the hepatic artery, whereupon they are then trapped preferably in the capillary network of the tumour.

This requires insertion of a catheter into the hepatic artery. As the liver tumours receive their blood supply practically exclusively through the hepatic artery, SIR-Spheres® are deposited in high amounts into the tumour(s) and not into the normal liver parenchyma, which is supplied by the hepatic artery and the portal vein.

As the maximal penetration depth of the beta-radiation delivered by the SIR-Spheres® measures 11 mm, the healthy liver will be only marginally irradiated.

The microspheres are implanted permanently. So far, no unwanted side effects have been noted. Animal experiments have shown that the microspheres are biocompatible, non-mutagenic, non-cell-poisoning and haemocompatible and do not cause any chromosomal aberration and are not locally or systemically toxic.

2. Aim of the treatment

The aim of the treatment with SIR-Spheres® is the reduction of the non resectable and with chemotherapy not treatable liver metastases.

3. Requirement for the treatment

- The patient is not a candidate for a possible healing by resection
- The liver is the main disease
- The patient is sufficiently healthy to endure the procedure
- The patient has a suitable arterial blood flow to the liver
- The percentage of the lung shunt is less than 20 %

To exclude complete resection of the tumour or healing, all patients treated with SIR-Spheres® are discussed interdisciplinary. Recent radiological images must be available in order to assess the tumour at the current stage and recent blood values of the liver have to be present.

Department of Nuclear Medicine, University Hospital

In approximately 3 % of patients with liver tumours, significant shunt circulation of the arterial and venous blood in the tumour will be present.

If these circulatory circuits are too pronounced, the inserted SIR-Spheres® can pass through the liver to the lungs. Since this can lead to radiation damage to the lungs, an examination (diagnostic angiography) has to be performed on all patients to exclude a significant shunt circulation.

For this purpose, a thin catheter will be inserted via the inguinal artery into the liver artery feeding the tumour. Then a micro particle, weakly radioactive, will be injected through this catheter. The radiation dose of this micro particle is in the range of a regular X-ray photograph. This distribution will then be measured by means of a high sensitivity method, the scintigraphy. If more than 20 % of the injected radioactivity will be found in the lungs, the circulatory circuits are too extensive and the patient cannot be treated with SIR-Spheres®.

In women of childbearing age, pregnancy must be excluded before any examination.

If all of these conditions are fulfilled, treatment with SIR-Spheres® is planned.

4. Therapy with SIR - Spheres®

The therapy with SIR-Spheres® is carried out at the earliest in the week following the scintigraphic evaluation. Again, a catheter will be inserted into the feeding arteries of the tumour. The therapeutic isotope yttrium-90 in the form of the SIR-Spheres® is subsequently introduced via this catheter. By entering via the tumour vessels locally, the microspheres deliver a high amount of radiation into the tumor mass. This local irradiation of the liver tumours exceeds the possible maximum of external irradiation by a factor of five. After the application of the SIR-Spheres®, you will be monitored on a ward.

Since the patient is still a little radioactive after being released home, large crowds, as well as longer, closer contact with relatives, especially pregnant women or small children, should be avoided for several days.

5. Benefits and risks

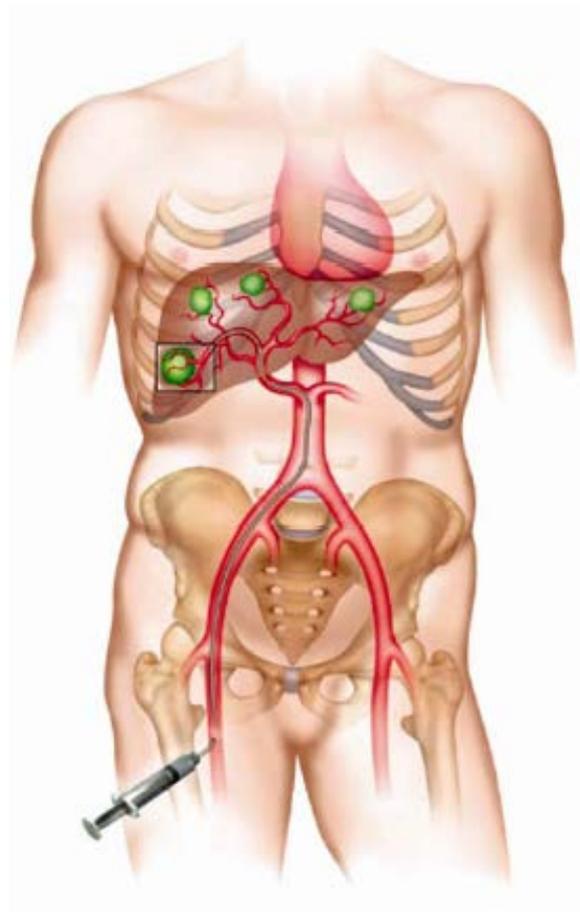
After the implantation of the SIR-Spheres®, approximately 50 % of patients develop a fever that can last a few days up to a week. The fever is related to the effect of the SIR-Spheres® on the tumour. Immediately following administration of SIR-Spheres®, in many patients body pain develops, which may have to be treated with pain medication. Some patients experience nausea, which can be treated with appropriate medication. Very rare, in < 1%, severe symptoms occur, such as radiation-induced stomach, pancreas or gut inflammation.

6. contacts

In case of any uncertainties, emergencies, unexpected or undesirable events occurring after the therapy, you can always contact one of the following persons:

Prof. Dr. Th. Pfammatter, Senior physician and Dr. Ivette Engel, Attending physician, University Hospital Zurich,
Phone: 044 255 35 55

Sketch:



Additional notes / sketches:

Consent form:

I, the undersigned, had taken note of this fact sheet and was informed by the doctor in a conversation about the diagnosis, type, course and risks of the SIR-Spheres® therapy in a way which I understand.

My questions have been answered to my satisfaction.

Thy clinical data can be evaluated anonymously in studies.

I agree to the Spheres® therapy.

Signature Patient

Place and date

Signature Physician

Place and date

For patients who cannot give the consent declaration themselves:

Signature Representative

Relationship

Place and date

Signature Physician

Place and date