

# **Prospective randomized controlled multicenter trial comparing transarterial chemoembolization (TACE) versus TACE plus radio frequency thermoablation for the treatment of hepatocellular carcinomas in patients on the waiting list for liver transplantation**

## **Principal Investigators:**

Pietro Majno, Unité de Transplantation, Département de Chirurgie, Hôpital Universitaire de Genève, Rue Micheli-du-Crest 24, 1211 Genève, tel 022-372776, fax 022-3727 707, email: [Pietro.Majno@hcuge.ch](mailto:Pietro.Majno@hcuge.ch)

Markus H. Heim, Abteilung für Gastroenterologie, Kantonsspital Basel, Petersgraben 4, 4031 Basel, tel 061 265 33 62, fax 061 265 53 52, email : [Markus.Heim@unibas.ch](mailto:Markus.Heim@unibas.ch)

Alban Denys, Département de Radiologie, CHUV, Rue du bugnon 46, CH-1011 Lausanne, tel 021-3144470, email: [Alban.Denys@chuv.hospvd.ch](mailto:Alban.Denys@chuv.hospvd.ch)

## **Co-Investigators:**

### ***Principle Local Investigators***

#### Basel:

Markus H. Heim, Abteilung für Gastroenterologie, Kantonsspital Basel, Petersgraben 4, 4031 Basel, tel 061 265 33 62, fax 061 265 53 52, email : [Markus.Heim@unibas.ch](mailto:Markus.Heim@unibas.ch)

#### Bern:

Jean-Francois Dufour, Institut für Klinische Pharmakologie, Inselspital, Murtenstrasse 35, 3010 Bern, tel. 031 632 87 29, email: [jf.dufour@ikp.unibe.ch](mailto:jf.dufour@ikp.unibe.ch)

#### Geneve:

Pietro Majno, Unité de Transplantation, Département de Chirurgie, Hôpital Universitaire de Genève, Rue Micheli-du-Crest 24, 1211 Genève, tel 022-372776, fax 022-3727 707, email: [Pietro.Majno@hcuge.ch](mailto:Pietro.Majno@hcuge.ch)

#### Lausanne:

Alban Denys, Département de Radiologie, CHUV, Rue du bugnon 46, CH-1011 Lausanne, tel 021-3144470, email: [Alban.Denys@chuv.hospvd.ch](mailto:Alban.Denys@chuv.hospvd.ch)

#### Lugano:

Andreas Cerny, Clinica Medica, Ospedale Civico, 6900 Lugano, email: [andreas.cerny@bluewin.ch](mailto:andreas.cerny@bluewin.ch)

Zürich:

Beat Müllhaupt, Abteilung Gastroenterologie, Dept. Innere Medizin, Universitätsspital Zürich, Rämistrasse 100, 8091 Zürich, email: beat.muellhaupt@dim.usz.ch

***Co-Investigators***

Augustinus Jacob, Institut f. Diagnostische Radiologie, Kantonsspital Basel, Petersgraben 4, CH-4031 Basel, tel. 061 265 43 76, 061 265 49 11, email: ajacob@uhbs.ch

Christian Seiler, Klinik für Viszerale und Transplantationschirurgie, Inselspital, CH-3010 Bern, email : christian.a.seiler@insel.ch

Christoph Becker, Departement de Radiologie, Hôpitaux Universitaires de Genève, 1211 Genève, Tel.: 022 372 70 97, Fax: 022 372 75 27  
email: christoph.becker@hcuge.ch

Jean-Jacques Gonvers, Policlinique médicale universitaire, Rue César-Roux 19, CH-1005 Lausanne, Tel.: 021 345 2222, email: Jean-Jacques.Gonvers@inst.hospvd.ch

Michel Gillet, Service de chirurgie générale, CHUV, CH-1011 Lausanne  
Tel.: 021 314 2424, email: Michel.Gillet@chuv.hospvd.ch

Zakiah Kardy, Klinik für Viszeral und Transplantationschirurgie, Universitätsspital Zürich, Rämistr. 100, 8091 Zürich, email: zakiah.kadry@chi.usz.ch

Thomas Pfammatter, Institut für Diagnostische Radiologie, Universitätsspital Zürich, Rämistr. 100, 8091 Zürich, email: thomas.pfammatter@usz.ch

Thomas Lacina, Ospedale Civico, 6900 Lugano, email : lacina@gmx.ch

Jürgen Triller, Institut für diagnostische Radiologie, Inselspital, CH-3010 Bern

Christoforos Stoupis, Institut für diagnostische Radiologie, Inselspital, CH-3010 Bern, email : christoforos.stoupis@insel.ch

## **Summary:**

Liver transplantation is an established treatment for patients with small hepatocellular carcinomas (HCC). During the waiting time on the transplant list most of the patients undergo one or several (neoadjuvant) treatments of their HCC, amongst them transarterial chemoembolization (TACE), percutaneous ethanol injection, and radiofrequency thermoablation. The aim of these treatments is to prevent tumor growth and invasion into hepatic vessels, contraindicating liver transplantation. The best treatment or combination of treatments to prevent tumor growth, however, is unknown. One of the most widely used treatments for HCC patients on the transplant waiting list is TACE. However, a substantial fraction of patients treated with TACE still have progressive tumor growth. Recently, percutaneous treatments of small hepatocellular carcinomas with radiofrequency thermoablation (RFTA) has been accepted as an effective local ablation therapy. The addition of RFTA to TACE treatment in HCC patients on the waiting list may reduce the number of patients with a tumor progression. The aim of this study is to compare the effect of neo-adjuvant TACE versus TACE + RFTA. The primary endpoint will be tumor progression beyond the standard criteria for liver transplantation. Secondary endpoints will be the drop out rate before transplantation, and the outcome of transplantation in terms of survival, disease free survival, and recurrence.