

Key Inclusion Criteria:

- Hepatocellular Carcinoma
- No more than 4 lesions
- At least 1 lesion \geq 3 cm and none $>$ 7 cm
- Child-Pugh A or B

Key Exclusion Criteria:

- Resectable HCC
- Scheduled for transplant
- Previous treatment for HCC
- Extrahepatic metastasis
- Other malignancy
- Encephalopathy
- Ascites

Study Sponsor:



10220-L Old Columbia Road • Columbia, MD 21046

For More Information Contact:

Professor Ronnie Tung Ping Poon

Department of Surgery
poontp@hku.hk

Ida Choi

Research Assistant
Department of Surgery
cychoia@hkucc.hku.hk

Queen Mary Hospital

Department of Surgery
102 Pokfulam Road
Hong Kong
Phone: (852) 2855 3635
Fax: (852) 2817 5475

For more information on the HEAT Study:
www.celsion.com
www.clinicaltrials.gov

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CLINICAL STUDY IN HEPATOCELLULAR CARCINOMA (HCC)

104-06-301

HEAT Study

Hepatocellular Carcinoma Study
of RFA and ThermoDox

A Phase III, Randomized, Double-Blinded,
Dummy-Controlled Study of the Efficacy and
Safety of ThermoDox® (Thermally Sensitive
Liposomal Doxorubicin) in Combination with
Radiofrequency Ablation (RFA) Compared to
RFA-Alone in the Treatment of Non-
Resectable Hepatocellular Carcinoma

Study Flow Chart
For Physician Reference Only

600 Subjects Randomized

OR

RFA Tx plus ThermoDox®
50mg/m², 30 minute IV infusion

RFA Tx plus D5W
30 minute IV infusion

- Day 14 ± 3 days
- 1, 3, 5, 7, 9, 12 months
- Every 3 months until subject discontinuation

Follow up visit

Ablation Assessment
Triphasic contrast CT

- 1 month after study Tx and
- 1, 3, 5, 7, 9, 12 months and then
- Every 3 months until subject disc.

Incomplete Ablation

Complete Ablation

- Retreat if eligibility criteria is met
- No earlier than 21 days after initial ablation
- No later than 14 days after first post ablation CT
- Unsuccessful ablation = treatment failure

Recur local and/or distant intra or extrahepatic HCC

✓ **Met Primary Endpoint**
Follow for Survival

Lesions amenable to RFA

Consider repeat RFA