Inclusion Criteria

Subjects must meet all of the following criteria to be included in this study:

1. Subjects must have confirmed diagnosis of unresectable HCC with any of following criteria:

o Histologically or cytologically confirmed diagnosis of HCC

o Clinically confirmed diagnosis of HCC according to American Association for the Study of Liver Diseases (AASLD) criteria, including cirrhosis of any etiology or with chronic hepatitis B or C infection criteria

2. At least 1 measurable target lesion according to mRECIST meeting the following criteria:

o Hepatic lesion

i) The lesion can be accurately measured in at least one dimension as ≥ 1.0 cm

ii) The lesion is suitable for repeat measurement

iii) The lesion shows intratumoral arterial enhancement on contrast-enhanced computed

tomography (CT) or magnetic resonance imaging (MRI)

o Nonhepatic lesion

i) Lymph node (LN) lesion that measures at least one dimension as ≥ 1.5 cm in the short axis,

except for porta hepatis LN that measures ≥ 2.0 cm in the short axis

ii) Nonnodal lesion that measures ≥ 1.0 cm in the longest diameter

Lesions previously treated with radiotherapy or locoregional therapy must show radiographic evidence of

disease progression to be deemed a target lesion.

3. Subjects categorized to stage B (not applicable for TACE, or progressed on locoregional therapy) or stage C based on Barcelona Clinic Liver Cancer (BCLC) staging system

4. Child-Pugh score A-B

5. Eastern Cooperative Oncology Group performance status (ECOG-PS) 0, 1, 2

6. Males or females aged at least 18 years (or any age greater than 18 years as determined by country legislation) at the time of informed consent.

7. Provide written informed consent

Exclusion Criteria

Subjects who meet any of the following criteria will be excluded from this study:

1.Subjects who have received any systemic chemotherapy, including sorafenib, or any systemic investigational anticancer agents, combining lenvatinib for advanced/unresectable HCC at the beginning of treatment.

3. Subjects who have received any anticancer therapy (including surgery, percutaneous ethanol injection, radio frequency ablation, transarterial [chemo] embolization, hepatic intra-arterial chemotherapy, biological, immunotherapy, hormonal, or radiotherapy) during the lenvatinib treatment.

4. Known intolerance to lenvatinib (or any of the excipients)

5. Any subject who cannot be evaluated by either triphasic liver CT or triphasic liver MRI because of allergy or other contraindication to both CT and MRI contrast agents

Diagnose Methods

		Number	Percentage	Effective Percentage	Accumulative Percentage
Effective	I	25	46.3	46.3	46.3
	Left liver-M, right liver- W	1	1.9	1.9	48.1
	M	7	13.0	13.0	61.1
	M-P	4	7.4	7.4	68.5
	P	7	13.0	13.0	81.5
	Well	10	18.5	18.5	100.0
	Total	54	100.0	100.0	

M, moderately differentiated; P, poorly differentiated; W, well differentiated; M-P, moderately-poorly differentiated; I, image diagnose.

AFP follow up

	Baseline AFP (ng/ml)	4-8 weeks	> 8 weeks
N Effective	54	54	39
Omit	0	0	15
Average		14317.9651	13474.6347
Median		761.0000	956.8000
Standard deviations		32325.59276	24713.41623
Variances		1044943947.411	610752941.839
Range		138107.00	83811.96
Minimum		14.00	51.04
Maximum		138121.00	83863.00

HBV diagnose: Hepatitis B diagnosis is a check of the five indicators of hepatitis B. If the surface antigen of hepatitis B is positive, it indicates that you are infected with hepatitis B virus, and you need to do further examinations of liver function, hepatitis B DNA and liver ultrasound.