ClinicalTrials.gov PRS DRAFT Receipt (Working Version)
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ClinicalTrials.gov ID: NCT04412161

Study Identification

Unique Protocol ID:	GGT-HCC-6CM
Brief Title:	Liver Transplant for Larger Hepatocellular Carcinoma in Malatya: The Role of GGT and AFP
Official Title:	Retrospective Cohort Study-Analysis of LT Patients With HCC (Maximum Tumor Diameter > 6 cm).
Secondary IDs:	

Study Status

Record Verification:	May 2020
Overall Status:	Completed
Study Start:	April 19, 2006 [Actual]
Primary Completion:	January 1, 2019 [Actual]
Study Completion:	December 1, 2019 [Actual]

Sponsor/Collaborators

Sponsor:	Inonu University
Responsible Party:	Principal Investigator Investigator: Volkan Ince [vince] Official Title: MD, FEBS, Assoc.Prof Affiliation: Inonu University
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Not required
Data Monitoring:	No
FDA Regulated Intervention:	No

Study Description

Brief Summary: Retrospective data on 50 prospectively-collected HCC patients with beyond-Milan criteria with >6cm tumors were analyzed. 5-year OS of 76.2% was found in patients with both AFP <200 ng/ml and GGT <104 IU/mL with tumors less than 10 cm diameter. Thus, GGT values add to AFP in patient prognosis.

Detailed Description: Background:A retrospective analysis was performed of prospectively-collected transplant data on outcomes of patients with large size HCCs,to examine possible prognostically-useful factors.Methods:A total of 50 patients having tumors greater than 6cm maximum diameter were identified. Their survival and full clinical characteristics were examined, with respect to serum AFP and GGT levels.Results:Using ROC analysis, cutoff values of AFP 200 ng/ml and GGT 104 IU/ml were identified and used in this study. Significantly longer overall-survival and disease-free-survival were found for patients who had lower values of either parameter, compared with higher values.Even greater differences in survival were found when the 2 parameters were combined, with best survival (5-year OS of 76,2% versus 0%, p=0.002).The most consistent clinical correlates for these longer survivals were degree of tumor differentiation and absence of microscopic portal venous invasion.Two tumor size bands were identified,to search for the limits of this approach with larger tumors, namely 6-10 and >10cm.Combination parameters in 6-10cm band reflected 5-year OS of 76,2% vs. 0%,in patients with low AFP plus low GGT vs. other groups.Beyond 10cm,no patients had low AFP plus low GGT.Conclusions:AFP and GGT,both singly and together, represent a simple prognostic identifier for patients with large size HCCs being treated by liver transplantation.

Conditions

Conditions: Hepatocellular Carcinoma
Liver Transplant Disorder

Keywords: Hepatic malignancy
GGT
living donor

Study Design

Study Type: Observational

Observational Study Model: Cohort

Time Perspective: Retrospective

Biospecimen Retention: None Retained

Biospecimen Description:

Enrollment: 50 [Actual]

Number of Groups/Cohorts: 1

Groups and Interventions

Groups/Cohorts	Interventions
Extra-Malatya Liver transplant patients with MTD>6 cm of HCC	Procedure/Surgery: Liver transplantation Living donor liver transplantation

Outcome Measures

Primary Outcome Measure:

1. overall and disease free survivals
   to analyse the factors that effect the survivals

   [Time Frame: five years follow up]

Eligibility

Study Population:	Liver transplant patients with maximum tumor diameter greater than 6 cm of hepatocellular carcinoma
Sampling Method:	Non-Probability Sample
Minimum Age:	
Maximum Age:	
Sex:	All
Gender Based:	No
Accepts Healthy Volunteers:	Yes
Criteria:	Inclusion Criteria: • Liver transplant patients with maximum tumor diameter greater than 6 cm of hepatocellular carcinoma Exclusion Criteria: • Early postoperative mortality (within 90 days) • Advanced stage tumors (explant patology revealed that tumor continues in the surgical cite such as positive lymph node metastases, macroscopic portal vein trombosis, diaphragmatic invasion, etc)

Contacts/Locations

Central Contact Person:	
Central Contact Backup:	
Study Officials:	
Locations:	

IPDSharing

Plan to Share IPD:	Undecided

References

Citations:	
Links:	
Available IPD/Information:	