厚生労働科学研究費補助金（がん臨床研究事業）
分担研究報告書

進行・再発肝細胞癌に対する動注化学療法と分子標的薬併用による新規治療法の確立を目指した臨床試験（PhaseIII）ならびに効果を予測するbiomarkerの探索研究研究

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研究要旨：外科的切除、局所壊死療法および肝動脈化学塞栓療法が適応とならない進行肝細胞癌患者を対象とし、ソラフェニブと低用量シスプラチン／フルオロウラシル肝動注の併用療法における全生存期間（OS）の延長をプライマリエンドポイントとして標準的治療であるソラフェニブ単独治療に対する優越性を検証する。

A. 研究目的

外科的切除、局所壊死療法および肝動脈化学塞栓療法が適応とならない進行肝細胞癌患者を対象とし、ソラフェニブと低用量シスプラチン／フルオロウラシル肝動注の併用療法における全生存期間（OS）の延長をプライマリエンドポイントとして標準的治療であるソラフェニブ単独治療に対する優越性を検証する。

B. 研究方法

外科的切除、局所壊死療法および肝動脈化学塞栓療法が適応とならない進行肝細胞癌患者を対象としたソラフェニブと Low-doseFP による肝動注化学療法の併用療法のソラフェニブ単独治療に対する優越性を確認する前向き、無作為化、非盲検、多施設共同、並行群間、第 III 相、比較臨床試験を行う。

（倫理面への配慮）

本試験に関係するすべての研究者は、ヘルシンキ宣言および「臨床研究に関する倫理指針」（平成２０年厚生労働省告示 第４１５号）に従って本試験を実施する。

C. 研究結果

本試験へ 4 例の患者登録を行い、試験を継続中である。

D. 考察

本年 12 月現在、142 ／190 例(74%)の登録となっており、試験完遂まで残り 48 例が未登録である。

E. 結論

本試験の目標登録数に向け、鋭意、登録、経過追跡を行っている。

F．健康危険情報

なし

G．研究発表

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H. 知的財産権の出願・登録状況

なし

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研究分担者　　辻　邦彦　手稲渓仁会病院　消化器病センター　副部長

研究要旨：外科的切除、局所壊死療法および肝動脈化学塞栓療法が適応とならない進行肝細胞癌患者を対象としたソラフェニブとLow-doseFPによる肝動注化学療法の併用療法のソラフェニブ単独治療に対する優越性を確認する前向き、無作為化、非盲検、多施設共同、並行群間、第III相、比較臨床試験

A. 研究目的

外科的切除、局所壊死療法および肝動脈化学塞栓療法が適応とならない進行肝細胞癌患者を対象とし、ソラフェニブと低用量シスプラチン／フルオロウラシル肝動注の併用療法における全生存期間（OS）の延長をプライマリエンドポイントとして標準的治療であるソラフェニブ単独治療に対する優越性を検証する。

B. 研究方法

外科的切除、局所壊死療法および肝動脈化学塞栓療法が適応とならない進行肝細胞癌患者に文書で同意を取得したうえで、ソラフェニブ単独治療群あるいはソラフェニブと Low-doseFP による肝動注化学療法の併用療法のどちらかの治療法へ無作為に割り付けを行い、プロトコールを順守して治療を施行する。プライマリエンドポイントは全生存期間（OS）とする。無増悪期間（TTP）、無増悪生存期間（PFS）、客観的奏効率（ORR）、腫瘍マーカーの変化（Tumor markers）、および安全性（Safety）を比較する。さらには付随研究として効果予測因子となるバイオマーカーを探索する。

（倫理面への配慮）

本試験に関係する研究は、ヘルシンキ宣言および「臨床研究に関する倫理指針」（平成２０年厚生労働省告示第４１５号）に従って実施している。なお、本試験は手稲渓仁会病院の諮問機関である当院倫理委員会（Ethics Committee）で審査され、手稲渓仁会病院の院長と倫理委員会から承認文書で承認済みである。

C. 研究結果

H24 年 12 月 16 日現在、全国で 136 例の症例が組み入れられ本試験を実施中である。当院では H24 年から参加したため現時点では登録症例がないが、現在、症例組み入れの準備中である。

D, E.　考察ならびに結論

本試験の解析により進行肝癌の治療に対する新たな選択肢が科学的に証明され、患者さんに福音となることが期待される。

Ｇ．研究発表

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肝癌に対するＲＦＡの長期予後とＶナビによる最新の治療支援について

辻　邦彦、友成暁子、山崎大

第16回日本肝臓大会　2012．10．10　神戸　ワークショップ1

非Ｂ非Ｃ型肝癌の現状と今後の展開

辻　邦彦、友成暁子、山崎大

H. 知的所有権の出願・取得状況

　なし

Ⅲ. 研究成果の刊行に関する一覧表

研究成果の刊行に関する一覧表

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Nishida N, Arizumi T, Hayaishi S, Takita M, Kitai S, Yada N, Hagiwara S, Inoue T, Minami Y, Ueshima K, Sakurai T, Ikai I, Kudo M	Gender differences in the livers of patients with hepatocellular carcinoma and chronic hepatitis C infection.	Digest Dis	30	547-553	2012
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Kudo M	Signaling pathway/molecular targets and new targeted agents under development in hepatocellular carcinoma.	World J Gastroenterol	18	6005-6017	2012
Kudo M	Japan's successful model of nationwide hepatocellular carcinoma surveillance highlighting the urgent need for global surveillance.	Liver Cancer	1(3)	141-143	2012
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Hagiwara S, Kudo M, Chung H, Ueshima K, Inoue T, Haji S, Watanabe T, Park AM, Munakata H, Sakurai T	Activation of c-Jun N-terminal kinase in non-cancerous liver tissue predicts a high risk of recurrence after hepatic resection for hepatocellular carcinoma.	Hepatol Res	42	394-400	2012
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Nishida N, Arizumi T, Takita M, Nagai T, Kitai S, Yada N, Hagiwara S, Inoue T, Minami Y, Ueshima K, Sakurai T, Ida H, Kudo M	Quantification of tumor DNA in serum and vascular invasion of human hepatocellular carcinoma.	Oncology	84	82-87	2013

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