201020010B

別紙１

厚生労働科学研究費補助金

がん臨床研究事業

# 進展型小細胞肺がんに対する予防的全脳照射のランダム化比較第Ⅲ相試験に関する研究

平成２０年度～平成２２年度　総合研究報告書

研究代表者　山本　信之

平成２３（２０１１）年　５月

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厚生労働科学研究費補助金（がん臨床研究事業）

（総合）研究報告書

# 進展型小細胞肺がんに対する予防的全脳照射のランダム化比較第Ⅲ相試験に関する研究

研究代表者　山本　信之　静岡県立静岡がんセンター呼吸器内科部長

研究要旨：進展型小細胞肺癌（SCLC）症例に対する予防的全脳照射（PCI）の有用性を検証するランダム化比較第III相試験を実施する

## A．研究目的

プラチナ併用初回化学療法に奏効した脳転移のない進展型SCLC症例に対するPCI療法が，非PCI療法に対して優れていることをランダム化比較にて検証すること．

進展型SCLCに対するPCIの有用性については，欧州から2007年にNew Engl J Med (357:664-672)に報告されたが，脳画像検査の追跡方法や治療方法が我が国の日常診療と大きく異なり、このエビデンスを我が国の日常診療にそのまま導入することは危険である．そこで，わが国の日常臨床に則して，進展型SCLCに対するPCIの有効性を検討する第III相試験を計画した．海外での臨床試験の結果を盲目的に導入することを避け，日本国内での日常臨床の指針を確立すること，そして参加施設が全国に広がることから全国的に質の高いがん医療水準の均てん化を推進することも目的としている．

## B．研究方法

本試験の主要エンドポイントは「全生存期間」，副次エンドポイントは「脳転移発生率」「無増悪生存期間」「有害事象」とする．

下記条件を満たす症例を対象とする．

1　小細胞肺癌に矛盾しない病理所見が得られている
2　進展型小細胞肺癌と診断されている
3　２コース以上のプラチナ併用初回化学療法に対して腫瘍縮小がみられた症例
4　登録前４週以内の脳MRI検査で脳転移が認められない．
5　登録前４週以内の胸腹部CT検査で腫瘍に増大傾向が認められない．
6　登録時年齢が20歳以上．
7　登録時PS（ECOG）が0－2．
8　初回化学療法最終コース開始日から登録までが６週以内．
9　PCIの照射野と重なる部位への放射線治療の既往がない
10　試験参加について患者本人から文書で同意が得られている

治療（PCI療法）は初回化学療法最終コース開始日から３～８週以内に以下の方法でPCIを行う：1回2.5Gy，1日1回，週5日，計10回，総線量25Gy，総治療期間12日間，許容総治療期間28日間

予定症例数は各群165例，両群計330例とする．

（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にしたがって本試験を実施し，説明と同意，個人情報の保護，第三者による監視について厳守する．

C．研究結果

下記に示す全国に広がる試験体制を確立し，2011年5月18日時点の総登録数は104例である．

＜試験参加施設＞

KKR 札幌医療センター，国立病院機構道北病院，北海道大学病院，旭川医科大学病院，国立病院機構北海道がんセンター，東北大学病院，宮城県立がんセンター，仙台厚生病院，福島県立医科大学医学部付属病院，国立がんセンター東病院，国立がんセンター中央病院，財団法人癌研究会有明病院，都立駒込横浜市立市民病院，埼玉県立がんセンター，北里大学医学部付属病院，順天堂大学医学部付属病院，神奈川県立循環器呼吸器病センター，茨城県立中央病院，群馬県立がんセンター，栃木県立がんセンター，国立病院機構西群馬病院，新潟県立がんセンター新潟病院，静岡県立静岡がんセンター，愛知県がんセンター中央病院，新潟大学医歯薬総合病院，国立病院機構名古屋医療センター，岐阜市民病院，厚生連高岡病院，名古屋市立大学病院，金沢大学医学部附属病院，大阪市立総合医療センター，近畿大学医学部附属病院，兵庫県立がんセンター，先端医療振興財団先端医療センター，大阪府立呼吸器・ｱﾚﾙｷﾞｰ医療ｾﾝﾀｰ，兵庫医科大学病院，神戸大学医学部付属病院，近畿中央胸部疾患センター，財団法人倉敷中央病院，広島市立市民病院，国立病院機構山口宇部医療センター，公立学校共済組合中国中央病院，住友別子病院，岡山赤十字病院，四国がんセンター，津山中央病院，国立病院機構九州がんセンター，岡山大学医学部・歯学部附属病院，国立病院機構九州がんセンター，国家公務員共済組合連合会浜の町病院，九州大学病院，熊本大学医学部付属病院，熊本地域医療センター，飯塚病院

D．考察

試験参加施設は全国に広がっており，各地域の肺がん診療の基幹病院である．本試験により得られたエビデンスは試験参加施設での医療のみならず，試験参加施設が存在する各地域全体での医療へ活かされるものと思われる．また，本試験以外でも試験参加施設のネットワークが活用される場面は多く，全国的に質の高いがん医療水準の均てん化を強力に推進することにつながると考えられる．

E．結論

症例集積を今後とも進めていく．

F．研究発表

1．論文発表

2．学会発表

本試験結果についての論文発表，学会発表はなし．

G．知的所有権の取得状況

1．特許取得

なし

2．実用新案登録

なし

3．その他

別紙４

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