厚生労働科学研究費補助金
がん臨床研究事業

再発小細胞肺がんに対する標準的治療法の確立に関する研究

平成18年度～20年度　総合研究報告書
1/2

研究代表者　後藤　功一

平成21（2009）年4月

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I.総合研究報告

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（総合）研究報告書

「再発小細胞肺がんに対する標準的治療法の確立に関する研究」

研究代表者　後藤　功一　国立がんセンター東病院　通院治療部医長

研究要旨

再発小細胞肺がんに対する標準治療の確立を目的に、標準治療と見なされているノギテカン(NGT)療法に対して、我が国で新しく開発されたシスプラチン＋エトポシド＋イリノテカン(PEI)療法の優越性を多施設共同第III相比較試験において検証する。本研究のプロトコールは、平成18年8月にJCOG(Japan Clinical Oncology Group)プロトコール審査委員会の承認を経て、平成18年9月20日より試験を開始した。厚生労働省がん研究助成金17指-2班の参加施設を中心に組織された38施設中、33施設で施設倫理委員会(IRB)の承認を得て、平成20年1月より本格的に症例登録が始まり、平成21年3月16日現在49例が登録されている。順調に症例集積中であり、今後約3年間で予定通り症例集積が完了すると推測される。

研究分担者

西條長宏	国立がんセンター東病院	副院長
田村友秀	国立がんセンター中央病院	部長
森　清志	栃木県立がんセンター	部長
岡本浩明	横浜市立市民病院	部長
野田和正	神奈川県立がんセンター	部長
横山　晶	新潟県立がんセンター新潟病院	副院長
樋田豊明	愛知県がんセンター中央病院	部長
今村文生	大阪府立病院機構 大阪府立成人病センター	部長
松井　薫	大阪府立呼吸器・アレルギー医療センター	医務局長
中川和彦	近畿大学医学部 内科学腫瘍内科部門	教授
武田晃司	大阪市立総合医療センター	部長
木浦勝行	岡山大学・医学部 医学部附属病院	准教授
河原正明	国立病院機構 近畿中央胸部疾患センター	部長
根来俊一	兵庫県立がんセンター	部長

A. 研究目的

再発小細胞肺がん（初回治療が奏効して、治療終了から90日以上経過して再発を認めたsensitive relapse）を対象にして、現在の標準的治療法と見なされるノギテカン(NGT)療法に対するシスプラチン＋エトポシド＋イリノテカン療法(PEI療法)の優越性を検証することを目的とする。

B. 研究方法

全国38施設の研究グループによる多施設共同第 III 相比較試験で、エンドポイントは生存期間である。生存期間中央値（MST）を8ヶ月から12ヶ月に向上させることを見込んでいる。

対象患者は、再発小細胞肺がん（初回治療が奏効して、治療終了から90日以上経過して再発を認めた sensitive relapse）であり、小細胞肺がんに対する外科的切除術の既往がなく、初回治療としてプラチナ製剤を含む併用化学療法または放射線化学療法を受けており、75 才以下、ECOG Performance Status（PS）0-2、主要臓器機能が保持されており、患者本人の自由意思による文書同意が得られた患者である。

JCOG データーセンターでの中央登録、無作為化割り付けを行う。なお、割付調整因子は、PS、再発時病期、施設である。

治療内容は、NGT 療法、あるいは PEI 療法を行う。NGT 療法は、ノギテカン 1.0 mg/m^2(day1-5)、3 週間隔、4 コースとする。PEI 療法は、第 1 週目：シスプラチン(25 mg/m^2, day 1)＋エトポシド(60 mg/m^2, day 1-3)、第 2 週目：シスプラチン(25 mg/m^2, day 1)＋イリノテカン(90 mg/m^2, day 1)の 2 週間を 1 コースとして 5 コース(計 10 週）の治療法である。PEI 療法は、1 コース目の第 8 日目より G-CSF を抗癌剤投与日以外は連日投与する。

最終解析は症例集積終了 1 年後、中間解析は 1 回、安全性モニタリングは原則年 2 回。予定症例数は 180 例で集積期間は 4 年を予定している。

(倫理面への配慮)

試験治療の安全性と効果は第 II 相試験で確認済みである。また適切な症例選択規準・治療中止規準の設置により個々の患者の安全性を確保するなど試験参加による不利益を最小限にするよう配慮した。また、ヘルシンキ宣言や米国ベルモントレポート等の国際的倫理原則および厚生労働省「臨床研究に関する倫理指針」に従い、以下を遵守する。(1)研究実施計画書（プロトコール）の施設 IRB 承認を必須とする。(2)すべての患者に説明文書を用いた十分な説明を行い、考慮の時間を設けた後、自由意思による同意を本人より文書で得る。(3)データの取り扱い上、直接個人が識別できる情報を用いず、データベースのセキュリティを確保し、個人情報（プライバシー）保護を厳守する。(4)プロトコール審査委員会、効果・安全性評価委員会、監査委員会を組織し、研究の第三者的監視を行う。

C. 研究結果

平成 18 年に厚生労働省がん研究助成金 17 指-2「呼吸器悪性腫瘍に対する標準的治療確立のための多施設共同研究」班の参加施設を中心とする全国の肺がん臨床研究の主要施設 38 施設で研究グループを組織した。

JCOG プロトコール作成支援機構および審査機構の協力を受け、JCOG 運営委員会において研究コンセプトが承認され、平成 18 年 8 月に JCOG プロトコール審査委員会の承認を経て、平成 18 年 9 月 20 日より本試験を開始した。施設 IRB の承認を得て、平成 20 年 1 月より本格的に症例登録が始まり、平成 21 年 3 月 16 日現在 49 例が登録されている。順調に症例集積中であり、今後約 3 年間で予定通り症例集積が完了すると推測される。

D. 考察

小細胞肺がんは全肺がんの 10-15%を占め、非小細胞肺がんに比べると化学療法や放射線療法の感受性が高く、初回治療に対する奏効率は限局型で 80-100%, 進展型で 60-80%である。しかし、80-90%の小細胞肺がんは再発を来し、5 年生存率は限局型で約 25%、進展型で 0-5%であり、小細胞がん全体の 5 年生存率は 10%未満と不良である。再発後の化学療法に対する反応は悪く、再発から死亡までの MST は 3-4 ヶ月と言われて来た。

近年、再発小細胞肺がんは、初回化学療法が奏効し、治療終了から 60-90 日以上経過して再発を認める sensitive relapse と、初回治療に奏効しない、あるいは奏効しても 60-90 日以内に再発を認める refractory relapse の 2 つに分類されて、臨床研究が行われてきた。これは、この 2 群で化学療法の効果や生存期間に差を認めるためである。例えば、NGT 療法でみると、奏効率、MST は、sensitive relapse では 14-37%、25-37 週、refractory relapse では 6-11%、16-20 週である。

現在までに再発小細胞肺がん(sensitive relapse)を対象とした 3 つの第 III 相試験が報告されている。NGT 療法とシクロホスファミド+アドリアマイシン+ビンクリスチン(CAV)療法を比較した第 III 相試験では、MST:25.0 週対 24.7 週と有意差を認めなかったが、再発に伴う症状の改善では NGT 療法が優れていた。NGT 療法の経口投与法と静脈投与法の比較試験では、奏効率、生存に有意差を認めず、毒性も同程度であった。また、NGT 療法の経口投与と無治療の第 III 相試

験では、NGT 療法の有意な MST の延長(26 週対 14 週)を認めた。再発小細胞肺がんに対する標準的化学療法は確立していないが、上記 3 つの第 III 相試験の結果に基づいて、世界的に NGT 療法が再発小細胞肺がんに対する標準治療とみなされている。そこで、再発小細胞肺がん(sensitive relapse)に対する標準治療の確立を目指して、NGT 療法と我々が開発した PEI 療法の第 III 相比較試験を開始した。

E. 結論

再発小細胞肺がんの予後改善を目的とした「再発小細胞肺がんに対する標準的治療法の確立に関する研究」では、「再発小細胞肺癌に対する NGT 療法と PEI 療法を比較する第 III 相試験(JCOG0605)」を平成 18 年 9 月 20 日より多施設共同試験として開始し、平成 21 年 3 月 16 日現在 49 例が登録され、順調に症例集積中である。

F. 研究発表

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II.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

書籍

著者氏名	論　文 タイトル名	書籍全体の 編集者名	書　籍　名	出版社名	出版地	出版年	ページ
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