厚生労働科学研究費補助金
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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　総括研究報告書

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総括研究報告書

「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」

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研究要旨

再発小細胞肺がんの予後改善を目的に、現在標準的と見なされているノギテカン療法に対して、我が国で新しく開発された治療法であるシスプラチン＋エトポシド＋塩酸イリノテカン療法(PEI 療法)の優越性を大規模第３相比較試験において検証するために、現在、プロトコールを作成中である。研究コンセプトは JCOG (Japan Clinical Oncology Group)運営委員会において承認されて、平成 18 年８月に一次審査に提出した。現在、一次審査での質問事項に対する回答を作成中です。平成 19 年度早々に二次審査を経てプロトコールの承認を得る予定です

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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症例）を対象にして、現在の標準的治療法と見なされるトポテカン単剤療法(Topotecan、国内ではNogitecan：以下ノギテカン療法(NGT療法))に対するシスプラチン＋エトポシド＋塩酸イリノテカン療法(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 37 施設の研究グループによる第３相無作為化試験で、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。

対象症例は、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症例）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を必須とする。

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、無作為化割り付け因子は、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1.0mg/㎡(5日間)、3週間隔、4コースをする。PEI療法はシスプラチン25mg/㎡、エトポシド60mg/㎡(3日間) 第1週、シスプラチン25mg/㎡、イリノテカン90mg/㎡ 第2週の2週間を1コースとして5コースまで施行して、1コース目の第8日目より G-SCF 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1年後、中間解析は1回、安全性モニタリングは年2回を予定している。予定症例数は180例で集積期間は4年を見込んでいる。

なお、倫理面の配慮に関してプロトコールに、(1)施設IRBの承認、(2)文書を用いた十分な説明後、被験者本人の自由意思による同意、(3)個人情報の厳守、(4)臨床試験審査委員会、効果･安全性評価委員会による監視を必須とする。

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37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月プロトコールを提出して一次審査を受けた。現在一次審査に対する回答を作成して二次審査に提出予定です。

D.考察

小細胞肺がんに対する現時点での標準的治療法は、進展型と限局型に分けてほぼ確立してきた。進展型では、我々がイリノテカン+シスプラチン(IP)療法の有用性を第3相試験において検証して、新しい標準的治療法を確立した。限局型では放射線療法の線量、分割方法、化学療法とのタイミングなどにも我々が関与して標準的治療法が確立して来た。

その結果、20年前と比較すると、生存期間中央値は進展型では7ヶ月から約12ヶ月に、限局型では14ヶ月から約24ヶ月に改善されて来ている。

しかし、再発に関する治療研究は少なかったが、最近、再発治療でのNGT療法の有用性を示す第3相比較試験が3つ報告された。

そこで我々が新しく開発したPEI療法と第3相比較試験を計画した。現在、プロトコールを作成中である。

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」は、研究グループ組織、データーセンター、臨床試験支援機構などが整備されて、プロトコールの作成中である。

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

1.特許取得

なし

2.実用新案登録

なし

3.その他

なし

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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