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がん臨床研究事業

限局型小細胞肺がんに対する新たな標準的治療の確立に関する研究

平成２２年度　総括研究報告書

研究代表者　田村　友秀

平成２３（２０１１）年　３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）
総括研究報告書

限局型小細胞肺がんに対する新たな標準的治療の確立に関する研究

研究代表者　田村　友秀　国立がん研究センター中央病院　呼吸器腫瘍科呼吸器内科長

研究要旨
限局型小細胞肺がんに対する次期第 III 相試験の試験治療を選択する目的で、「エトポシド＋シスプラチン療法 1 コースと加速多分割胸部放射線療法の同時併用後の、シスプラチン＋ビンクリスチン＋ドキソルビシン＋エトポシド療法とアムルビシン＋シスプラチン療法のランダム化第 II 相試験」の症例登録を本年より開始した。事前に実施した「安全性確認試験」の最終解析では、アムルビシンを含む治験群の安全性と良好な効果が確認できた。

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A．研究目的

限局型小細胞肺がんを対象として、
(1)「エトポシド＋シスプラチン（EP）療法 1 コースと加速多分割胸部放射線療法（AH-TRT）の同時併用（EP/AH-TRT）後のアムルビシン＋シスプラチン（AC）療法の安全性確認試験を行い、実施可能性を確認する。
(2)EP/AH-TRT 後の、シスプラチン＋ビンクリスチン＋ドキソルビシン＋エトポシド（CODE）療法と AC 療法のランダム化第 II 相試験」を実施し、次期第 III 相試験の試験治療群を選択する。

B．研究方法

(1) EP/AH-TRT 後の AC 療法の安全性確認試験
ランダム化第 II 相試験の治療群のひとつとなる EP/AH-TRT 後の AC 療法の安全性を確認する。6 症例で忍容性を評価し、その後 6-15 例を追加して安全性を確認する。
(2) ランダム化第 II 相試験
全国 38 施設の多施設共同試験とし、主要評価項目は 1 年無増悪生存割合とする。対象は、限局型かつ初回治療の小細胞肺がんで、70 才以下、ECOG Performance Status (PS) 0-1、測定可能病変を有し、主要臓器機能が保持された症例とする。
治療内容は、EP/AH-TRT を実施後、CODE 療法 6 週間あるいは AC 療法 3 コースの治療を実施する。

EP 療法：　エトポシド　100 mg/m² day 1,2,3
　　シスプラチン　80 mg/m² day 1
加速多分割胸部放射線療法(AH-TRT)：45Gy/30fr./3weeks
CODE 療法：　シスプラチン　25mg/m² week 1-6
　　ビンクリスチン　1mg/m² week 2, 4, 6
　　ドキソルビシン 40mg/m² week 1, 3, 5
　　エトポシド　80mg/m² x3d week 1, 3, 5
AC 療法：　アムルビシン　40mg/m² day 1-3
　　シスプラチン　60mg/m² day 1
3 週毎に 3 コース

予定症例数は、80例、集積期間は2年、追跡5年とする。

（倫理面の配慮）

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、臨床研究に関する倫理指針（平成21年厚生労働省）に従い以下を遵守する。(1)各施設IRB承認を必須とする。(2)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)直接個人を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)臨床試験審査委員会、効果・安全性評価委員会を組織し、研究の第三者的監視を行う。

C．研究結果

(1)EP/AH-TRT後のAC療法の安全性確認試験の最終解析結果

平成20年に安全性評価予定の6例の登録を終了し、平成21年に計21例の登録を完了した。本年度は、生存期間を含めた最終解析を行った。21例全例がEP/AH-TRTを完了し、18例（86%）がその後のAC療法3コースを完遂した。主な毒性は血液毒性であり、Grade 4の好中球減少は17例（81%）に認められた。発熱性好中球減少を9例に認めたが、うち5例で持続期間は1日のみであった。G-CSFは16例に投与された。治療関連死はなかった。抗腫瘍効果では、奏効率95%であった。観察中の症例の観察期間中央値は22.8か月（17-40）であり、1年/2年無再発生存割合は62%/52%、1年/2年生存割合は95%/81%であった。

(2)ランダム化第II相試験の症例登録開始

平成20年にJCOG運営委員会でプロトコールコンセプトの承認を受け、平成21年にJCOGプロトコール審査委員会に実施計画書の審査を申請した。平成23年3月に最終承認を得、症例登録を開始した。平成24年度中に症例集積を完了する予定である。

D．考察

我々は、限局型小細胞肺がんに対する標準的治療として、EP/AH-TRT療法後EP3コースの治療法を確立した。次いでEP/AH-TRT療法後のIP3コースの治療を考案し、有用性を検証する第III相試験（JCOG0202）の登録を完了した。最終解析は平成23年に予定している。今回、評価するEP/AH-TRT療法後のCODE療法あるいはIP3コースは、いずれも日本で考案された、現時点で最も期待される治療法といえる。EP/AH-TRT療法後のIP3コースの安全性確認試験では、血液毒性は高度であるものの、忍容可能と判断した。また無増悪生存期間、全生存期間はいずれも良好であった。ランダム化第II相試験は、ようやく症例登録を開始することができた。平成24年度中に登録を完了する見込みである。

我々は、新たな治療法の確立によって、5年生存率が現状より10%程度向上することを期待している。我が国の全肺がん死亡数は年間5万人にのぼる。小細胞肺がんは全肺がんの約15%を占め、その半数は限局型である。限局型小細胞肺がんの治癒率の向上は国民福祉への多大なる貢献であると同時に、再発後の化学療法、姑息的放射線療法、支持療法とこのための入院などの医療費を削減する経済的効果も大きいと思われる。さらにこの成果は、世界のトップにある我が国の肺がん治療のレベルの高さを改めて世界に示すこととなり、医療の発展のための国際協調の中で極めて大きな貢献となると考える。

E．結論

EP/AH-TRT後のAC療法の安全性確認試験の最終解析において、安全性と有効性を確認した。ランダム化第II相試験の実施計画書が平成23年3月に承認され、症例登録を開始した。

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
(予定も含む)

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

雑誌

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