Nimotuzumab- Cáncer de cabeza y cuello

---------- Título abreviado del estudio:
Nimotuzumab- Cáncer de cabeza y cuello
---------- Título completo del estudio:
Uso del Anticuerpo monoclonal Nimotuzumab en el tratamiento de pacientes con Carcinoma de Células Escamosas de Cabeza y Cuello,en estadíos avanzados.
---------- Palabras claves:
Nimotuzumab,Carcinoma de Células Escamosas,Cabeza y Cuello.
---------- Identificadores del ensayo:
IIC RD-EC0113,Centro de Inmunología Molecular(CIM)
---------- Promotor principal:
Centro de Inmunología Molecular(CIM)
---------- Otros promotores:
No Procede
---------- Participación del CENCEC en el ensayo:
1. Servicio completo
---------- Fuentes de financiamiento del estudio:
Reserva Estatal
---------- Agencia reguladora que aprueba el inicio del ensayo:
Centro para el Control Estatal de la Calidad de los Medicamentos(CECMED),Notificación,24-081-08-B
---------- Fecha de la autorización de inicio por Agencia reguladora:
26/12/2008 00:00
---------- Número de referencia en la agencia reguladora:
24-081-08-B
---------- Estado del producto:
2. Producto registrado en la indicación
---------- Agencia que registró el producto:
Centro para el Control Estatal de la Calidad de los Medicamentos(CECMED)
---------- Número de registro sanitario:
1745-C
---------- Fecha de registro sanitario:
19/02/2002 00:00
---------- Países de reclutamiento:
Cuba
---------- Provincia del Sitio clínico principal:
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---------- Nombre del Sitio clínico principal:
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Ciudad Habana,Hospital“Hermanos Ameijeiras”,8 de Diciembre de 2008.
Ciudad Habana,Centro de Investigaciones Médico-Quirúrgicas(CIMEQ),14 de Mayo de 2009.
Ciudad Habana,Instituto Nacional de Oncología y Radiobiología(INOR),22 de Junio de 2009.
Ciudad Habana,Hospital “Enrique Cabrera”,17 de Octubre de 2008.
Villa Clara,Hospital “Celestino Hernández Robau”,28 de Julio de 2008.
Camaguey,Hospital “María Curie”,13 de Octubre de 2008.
Holguín,Hospital“Vladimir Ilich Lenin”,25 de Agosto de 2008.
Santiago de Cuba,Hospital“Conrado Benítez”,21 de Julio de 2008.
---------- Etapa del Ensayo:
2. En Ejecución
---------- Causa de terminación temprana:
---------- Estado del reclutamiento:
2. En reclutamiento
---------- Fecha del primer incluido:
06/01/2009 00:00
---------- Fecha del último incluido:
30/01/2010 18:00
---------- Total de pacientes incluidos:
94
---------- Condición médica que se estudia:
Carcinoma de Células Escamosas de Cabeza y Cuello,en estadíos avanzados.
---------- Tipo de la intervención:
3. Biológicos/Vacunas
---------- Breve descripción de la(s) intervención(es):
Esquemas de tratamiento:
1.Esquema A: Nimotuzumab + RT
2.Esquema B: Nimotuzumab + RT + QT,concurrente
3.Esquema C: Nimotuzumab + RT + QT,secuencial
4.Esquema D: Monoterapia con Nimotuzumab
5.Esquema E: Nimotuzumab + QT
Indicación de Nimotuzumab: 200 mg en infusión intravenosa(IV),(30-60 minutos,diluído en 250 ml de NaCl 0.9%)
Fase de inducción: 1 vez a la semana durante 6 semanas.
Fase de Mantenimiento:Cada 21 días hasta la interrupción del tratamiento por al menos una de las causas previstas en el Protocolo de Investigación.
Indicación de Radioterapia(RT): Dosis:66 Gy
El esquema podrá involucrar Co60, Acelerador lineal o fraccionado 2 Gy/diarios,días 1-5 de la semana (lunes-viernes) hasta completar la dosis indicada.
Indicación de Quimioterapia(QT): Cisplatino 100 mg/m2 endovenoso(EV) + 5-FU 1000 mg/m2.
Frecuencia y Duración del Tratamiento:
Tratamiento concurrente: días 1, 22 y 43
Tratamiento secuencial: cisplatino día 1, 5-FU días 1-4 de la semana(lunes-jueves) cada 3 ó 4 semanas por 3 ciclos.
---------- Total de grupos:
5 esquemas de tratamiento con Nimotuzumab
---------- Propósito primario de la intervención:
1. Tratamiento
---------- Otro propósito primario del estudio:
---------- Objetivos del ensayo:

General:
1.Evaluar la seguridad y efectividad del Nimotuzumab en pacientes portadores de CCECC,en estadíos avanzados.
Específicos:
1.Determinar la incidencia de eventos adversos relacionados con la administración del Nimotuzumab (con relación causal probable o muy probable).
2.Evaluar la respuesta clínica en los pacientes tratados.
3.Determinar la sobrevida libre de progresión y la sobrevida global.
4.Evaluar la calidad de vida de los pacientes tratados.
---------- Tipo de objetivo a evaluar:
3. Seguridad/eficacia
---------- Otro tipo de objetivo:
---------- Hipótesis del EC:
Se espera que la incidencia de eventos adversos con relación causal probable o muy probable con respecto al Nimotuzumab,reportados en un período de 2 años,no supere el 31%.
---------- Variable(s) Primaria(s):
Incidencia de Eventos Adversos (EA) relacionados con la administración del Nimotuzumab (EA con relación causal probable o muy probable). Tiempo de Medición: trimestral hasta completar 2 años de tratamiento.
---------- Variables Secundarias:
Respuesta Clínica (Respuesta objetiva y respuesta clínica antitumoral). Tiempo de medición: cada 3 meses hasta completar 2 años de tratamiento.
- Respuesta objetiva (Enfermedad medible y enfermedad no medible)
- Enfermedad medible (Respuesta Completa, Respuesta Parcial, No cambio, Progresión)
- Enfermedad no medible (Respuesta Completa, Respuesta Parcial, Estabilización, Progresión)
- Respuesta Clínica Antitumoral (Respuesta Completa, Respuesta Parcial, Enfermedad Progresiva, Enfermedad Estable)
Supervivencia libre de progresión (SLP). Tiempo, en meses, transcurrido desde la inclusión del paciente hasta la documentación objetiva de la enfermedad progresiva o la muerte. Tiempo de Medición: 2 años de tratamiento o antes si ocurre la progresión o la muerte.
Supervivencia Global. Tiempo, en meses, desde la inclusión del paciente hasta su fecha de fallecimiento o última fecha que se tiene noticias. Tiempo de Medición: 2 años de tratamiento o antes si ocurre la muerte.
Calidad de Vida (Cuestionario de Calidad de Vida EORTC QLQ-C30 (versión 3) y QLQ-H&N35 (versión 3). Cada 3 meses hasta completar los 2 años de tratamiento.
Eventos Adversos (EA). Tiempo de medición: 2 años de tratamiento
- Descripción del EA (Nombre del evento adverso).
- Tiempo entre el momento de la administración y la aparición del EA (horas y minutos o días)
- Duración del EA (Diferencia de fechas entre el inicio y la terminación del evento. Puede ser en días, horas o minutos)
- Seriedad del EA(Grave/serio, No grave/no serio)
- Intensidad del EA (Grado 1:Ligero, Grado 2:Moderado, Grado 3:Severo, Grado 4:Peligro para la vida, Grado 5:Muerte)
-Relación de causalidad (Remota, Posible, Probable, Muy Probable) considerando criterios de la FDA
- Posible tratamiento causal (nombre del tratamiento que ocasionó el evento, si se considera que el EA se debió a la administración del Nimotuzumab, de la QT y/o RT o de algún otro tratamiento concomitante)
- Actitud seguida ante la aparición del EA (sin cambios, modificación de dosis, interrupción temporal, interrupción definitiva del tratamiento en estudio)
- Resultado del EA (recuperado, mejorado, persiste, secuelas)
---------- Género:
3. Ambos
---------- Edad mínima:
18 años

---------- Edad máxima:
Ninguna
---------- Criterios de Inclusión:
1.Edad mayor o igual que 18 años.
2.Expectativa de vida de al menos 12 semanas.
3.Estado general según ECOG 0-2.
4.Pacientes que otorguen su consentimiento de participación en el estudio por escrito.
---------- Criterios de Exclusión:
1.Paciente que al momento de la inclusión esté recibiendo otro medicamento en investigación.
2.Embarazo,puerperio o en lactancia.
3.Antecedentes de hipersensibilidad a alguno de los componentes de la formulación farmacéutica del Nimotuzumab.
4.Presencia de un segundo tumor primario, con la excepción de carcinomas basal o escamoso de piel y carcinoma in situ de cuello tratado.
---------- Tipo de participante:
2. Enfermos
---------- Aleatorización:
1. Aleatorizado
---------- Enmascaramiento:
1. Abierto
---------- Grupo control:
3. No controlado
---------- Diseño:
1. Un solo grupo
---------- Otro diseño:
---------- Otros detalles del diseño:
5 esquemas de tratamiento con Nimotuzumab
---------- Fase:
6. Fase IV
---------- Tamaño de muestra:
Inclusión a 2 años.
---------- Nombre de la persona a contactar (para inquietudes generales):
Dra.Patricia Piedra
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---------- Resultados:
---------- Modificaciones Realizadas al Protocolo:
---------- Aprobaciones a las Modificaciones Realizadas por los Comités de Etica:
---------- Nombre del Registro Público:
RPCEC
---------- Código del Registro Público:
RPCEC00000089
---------- Fecha en que se registra el ensayo:
22/10/2009 20:00
---------- Fecha de última actualización:
27/08/2009 20:00
Instrucciones: Complete los datos que se encuentran clasificados en pestañas. Para moverse entre las pestañas use los botones "siguiente" y "anterior". Puede almacenar los datos en cualquier momento con el boton "guardar".:

Agregar un Comentario