ForPatients
by Roche

Neoplasm MetastasisCáncer

An Extension Study of trastuzumab emtansine administered as a single agent or in combination with other anti-cancer therapies in patients previously enrolled in a Genentech and /or F. Hoffmann-La Roche Ltd. – sponsored trastuzumab emtansine study

A Safety Extension Study of Trastuzumab Emtansine in Participants Previously Treated With Trastuzumab Emtansine Alone or in Combination With Other Anti-Cancer Therapy in One of the Parent Studies

Trial Status	Trial Runs In	Trial Identifier
Activo, no admitiendo	35 Countries	NCT00781612 BO25430 2010-021067-32 2023-503479-79-00 TDM4529g

La información se obtuvo directamente de sitios web de registros públicos, como ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., y no se ha editado.

Official Title:

Estudio de extensión, multicéntrico, abierto de trastuzumab emtansina administrado como agente único o en combinación con otras terapias antineoplásicas en pacientes incluidos previamente en un estudio de trastuzumab emtansina patrocinado por Genentech y/o F. Hoffmann-La Roche Ltd

Trial Summary:

Este es un estudio de extensión de seguridad global, multicéntrico, abierto. Se consideran elegibles para continuar el tratamiento en este estudio a los participantes que reciben trastuzumab emtansina como agente único o trastuzumab emtansina administrado en combinación con otros agentes en un estudio original patrocinado por Genentech/Roche que estén activos y obtengan beneficios al cierre del estudio original.

Genentech, Inc.	Fase 2
Sponsor	Phase

NCT00781612 BO25430 2010-021067-32 2023-503479-79-00 TDM4529g
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

1. Why is this study needed?

Breast cancer is a health condition where cancer cells form in the breast. Breast cancer can sometimes be diagnosed as ‘metastatic’. Metastatic cancer is cancer that has spread to other parts of the body. Some cancers have more human epidermal growth factor receptor 2 (HER2) than normal. HER2 is a protein involved in normal cell growth. When cancers are ´HER2-positive’, the extra HER2 causes cancer cells to grow more quickly. Better treatments are needed for HER2-positive breast cancers that have spread to other parts of the body.

This study is testing a medicine called trastuzumab emtansine on its own and combined with other anti-cancer medicines (atezolizumab, pertuzumab, docetaxel and paclitaxel).

Trastuzumab emtansine on its own is approved in some countries by health authorities like the U.S. Food and Drug Administration and European Medicines Agency. This is for HER2-positive breast cancer that has been treated with trastuzumab and another type of anti-cancer medicine called a taxane. Atezolizumab is approved in some countries for treating a type of breast cancer called ‘triple negative breast cancer’ that has spread. It is not approved for treating HER2-positive breast cancer. Pertuzumab in combination with trastuzumab is approved in some countries for treating HER2-positive breast cancer that has spread. Pertuzumab combined with trastuzumab and either docetaxel or paclitaxel are also approved in some countries to treat HER2-positive breast cancer. This includes cases with or without spread.

Trastuzumab emtansine combined with other anti-cancer medicines are experimental treatments. This means health authorities have not approved these combinations for the treatment of HER2-positive breast cancer. This study aims to continue to assess the safety of trastuzumab emtansine. It will be studied on its own and combined with other anti-cancer medicines. The study will include people with HER2-positive breast cancer that has spread. Participants must have benefited from trastuzumab emtansine or trastuzumab treatment in a Genentech and/or F. Hoffmann-La Roche Ltd–sponsored study (called a parent study).

2. Who can take part in the study?

People of 18 years of age or older with HER2-positive breast cancer that has spread can take part in the study. But only if they have completed treatment in a parent study within the last 6 weeks. They must be expected to benefit from being given trastuzumab emtansine or from continuing their study treatment. They must also not be able to access their study treatment elsewhere.

People may not be able to take part in this study if their cancer got worse during the parent study. People who had unwanted effects from study medicines that were serious or caused them to stop treatment also cannot take part. People who are pregnant, or currently breastfeeding cannot take part in the study.

3. How does this study work?

Participants will be screened to check if they are able to participate in the study. The screening period will take place from 1 day to 1 month before the start of treatment.

Everyone who joins this study will continue to receive the same study treatment they were given during the parent study. Treatment will be once a week or once every 3 weeks instead if participants agree. If a participants' cancer got worse when being given trastuzumab and docetaxel in the parent study, they may be given trastuzumab emtansine instead. If participants no longer benefit from trastuzumab and docetaxel during this study, they may get trastuzumab emtansine. This includes those who have unacceptable unwanted effects. Study treatment will be given as often as it was given during the parent study.

This is an open-label study. This means everyone involved, including the participant and the study doctor, will know the study treatment the participant has been given.

During this study, the study doctor will see participants regularly to see how well the treatment is working and any unwanted effects participants may have. Participants will have a follow-up visit within 1 month of stopping study treatment, during which the study doctor will check on the participant's wellbeing. Participants who can get pregnant will also have 2 follow-up visits 3 and 7 months after stopping study treatment. Total time of participation in the study could be more than 1 month. Participants have the right to stop study treatment and leave the study at any time, if they wish to do so. Participants will not lose access to regular care if they stop study treatment.

4. What are the main results measured in this study?

The main results measured in the study to assess if the medicines have worked are:

- The number of participants who have unwanted effects and serious unwanted effects
- The number of participants who stop study treatment or have a lower dose of study treatment due to unwanted effects

5. Are there any risks or benefits in taking part in this study?

Taking part in the study may or may not make participants feel better. But the information collected in the study can help other people with similar health conditions in the future.

It may not be fully known at the time of the study how safe and how well the study treatment works. The study involves some risks to the participant. But these risks are generally not greater than those related to routine medical care or the natural progression of the health condition. People interested in taking part will be informed about the risks and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible effects and other options of treatment.
Risks associated with the study medicines Participants may have unwanted effects of the medicines used in this study. These unwanted effects can be mild to severe, even life-threatening, and vary from person to person. During this study, participants will have regular check-ups to see if there are any unwanted effects.
Trastuzumab emtansine, atezolizumab, pertuzumab, trastuzumab, docetaxel and paclitaxel Participants will be told about the known unwanted effects of trastuzumab emtansine, atezolizumab, pertuzumab, trastuzumab, docetaxel and paclitaxel, and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. Known unwanted effects include difficulty breathing while resting, feeling tired or weak, having a lack of energy, rash, fever, a feeling of coldness that makes the body shiver, cough, difficulty sleeping, throwing up and wanting to throw up.

Trastuzumab emtansine, atezolizumab, pertuzumab, trastuzumab, docetaxel and paclitaxel will be given as a drip into a vein (infusion). Known unwanted effects of drips into a vein include itching, rash, throat pain, reddening of the skin, headache, fever, a feeling of coldness that makes the body shiver, feeling tired or weak, throwing up and wanting to throw up.

The study medicine(s) may be harmful to an unborn baby. Women and men must take precautions to avoid exposing an unborn baby to the study treatment.

Inclusion Criteria:

- Aquellos que completaron el tratamiento con trastuzumab emtansina como agente único o trastuzumab emtansina en combinación en el estudio original o que siguen recibiendo tratamiento con trastuzumab emtansina como agente único o trastuzumab emtansina en combinación en el momento del cierre del estudio original y que recibieron la última dosis de medicamento del estudio en las 6 semanas (42 días) previas a la primera dosis de terapia del estudio en el estudio de extensión o que siguen recibiendo tratamiento en el grupo de referencia del estudio BO21976 / TDM4450g (NCT00679341) en el momento del cierre del estudio original si el participante recibió la última dosis del medicamento del estudio del grupo de referencia en las 6 semanas (42 días) previas a la primera dosis de terapia de estudio del grupo de referencia en el estudio de extensión
- Los participantes en el grupo de referencia del estudio BO21976/TDM4450g cuya progresión de la enfermedad se produjo durante el intervalo de transición entre el estudio original y este estudio de extensión pueden iniciar el tratamiento con trastuzumab emtansina en el momento del reclutamiento en el estudio TDM4529g (NCT00781612)
- Que el investigador considere que el participante pueda continuar beneficiándose del tratamiento con trastuzumab emtansina como agente único o trastuzumab emtansina en combinación o que el investigador considere que el participante pueda continuar beneficiándose del tratamiento del grupo de referencia tal como se administró en el estudio BO21976/TDM4450g y que en el momento de la

progresión de la enfermedad puede beneficiarse del tratamiento con trastuzumab emtansina como agente único
- Las mujeres con capacidad de concebir y los hombres con parejas con capacidad de concebir deben estar dispuestos a utilizar un método anticonceptivo no hormonal altamente eficaz o dos métodos anticonceptivos no hormonales eficaces por parte de los participantes y/o pareja y continuar con el uso de anticonceptivos durante el tratamiento del estudio y durante al menos 7 meses después de la última dosis del tratamiento del estudio
- Los participantes de sexo masculino cuyas parejas están embarazadas deben usar condones durante el embarazo.

Exclusion Criteria:

- EA que llevan a la discontinuación del tratamiento con trastuzumab emtansina como agente único o trastuzumab emtansina en combinación en el estudio original
- EAS en curso del estudio original
- Enfermedad progresiva en el régimen que contenga trastuzumab emtansina como agente único o trastuzumab emtansina en combinación durante el estudio original o antes de comenzar el estudio de extensión, a excepción de los participantes del estudio TDM4688g (NCT00943670) con progresión temprana de la enfermedad que recibieron tratamiento con pertuzumab + trastuzumab emtansina y no han experimentado más progresión de la enfermedad en el régimen de combinación
- Neuropatía periférica de grado mayor o igual a (>/=) 3 según los Criterios de terminología común para eventos adversos del Instituto Nacional del Cáncer (NCI CTCAE), versión 3.0 o 4.0, como se utilizó en el estudio original
- Antecedentes de insuficiencia cardíaca congestiva sintomática ([CHF]; Asociación del Corazón de Nueva York [NYHA] Clases II-IV), arritmia ventricular que requiere tratamiento, angina inestable en curso o antecedentes de infarto de miocardio en los 6 meses anteriores al ingreso al estudio
- Disnea grave en reposo debida a complicaciones de neoplasia avanzada o necesidad actual de oxigenoterapia continua
- Enfermedad sistémica en curso, grave no controlada (por ejemplo, enfermedad cardiovascular, pulmonar o metabólica clínicamente significativa)
- Procedimiento quirúrgico importante o lesión traumática significativa en los 28 días anteriores al ingreso al estudio o la anticipación de la necesidad de una cirugía importante durante el curso del tratamiento del estudio
- Embarazo o lactancia en curso
- Antecedentes de haber recibido cualquier tratamiento en investigación u otra terapia sistémica enfocada a controlar el cáncer (p. ej., quimioterapia, trastuzumab, etc.) desde la última dosis del medicamento del estudio que recibió el participante en el estudio original
- Antecedentes de hipersensibilidad previa a trastuzumab emtansina o cualquier agente que se utilice con trastuzumab emtansina en el estudio original, que excluya la dosificación de dosis adicionales
- Evaluado por el investigador como incapaz o no dispuesto a cumplir con los requisitos del protocolo