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## A Study of Loading Doses of Intravenous Bondronat (Ibandronate) in Patients With Breast Cancer and Malignant Bone Disease.

**This study is currently recruiting participants.**

Verified by Hoffmann-La Roche, December 2007

<b>Sponsored by:</b>	<b>Hoffmann-La Roche</b>
<b>Information provided by:</b>	Hoffmann-La Roche
<b>ClinicalTrials.gov Identifier:</b>	NCT00502736

### ► Purpose

This single arm study will assess the efficacy and safety of loading doses of intravenous Bondronat in patients with breast cancer and malignant bone disease experiencing moderate to severe bone pain. Patients will receive an intravenous infusion of 6mg Bondronat on days 1, 2 and 3. The anticipated time on study treatment is 3 months, and the target sample size is <100 individuals.

<a href="#">Condition</a>	<a href="#">Intervention</a>	<a href="#">Phase</a>
Pain; Bone Neoplasms; Neoplasm Metastasis	Drug: ibandronate [Bondronat]	<b>Phase II</b>

[Genetics Home Reference](#) related topics: [Bone Cancer](#)

[MedlinePlus](#) related topics: [Bone Cancer](#) [Cancer](#) [Pain](#)

[ChemIDplus](#) related topics: [Ibandronic acid](#)

[U.S. FDA Resources](#)

Study Type: Interventional

Study Design: Treatment, Non-Randomized, Open Label, Uncontrolled, Single Group Assignment, Safety/Efficacy Study

Official Title: An Open Label Study to Assess the Effect of Intravenous Loading Doses of Bondronat on Bone Pain in Patients With Breast Cancer and Skeletal Metastases

#### **Further study details as provided by Hoffmann-La Roche:**

Primary Outcome Measures:

- Pain and analgesic consumption on days 1, 7 and 14.

Secondary Outcome Measures:

- Safety: AEs, serum creatinine, laboratory parameters.

#### **► Eligibility**

Ages Eligible for Study: 18 Years and older

Genders Eligible for Study: Female

#### **Criteria**

Inclusion Criteria:

- female patients,  $\geq 18$  years of age;
- breast cancer;
- bone metastases;
- moderate to severe pain;
- adequate renal function.

Exclusion Criteria:

- bisphosphonate treatment within 3 weeks of study enrollment.

## ▶ **Contacts and Locations**

Please refer to this study by its ClinicalTrials.gov identifier: NCT00502736

### **Contacts**

Contact: Please reference Study ID Number: RLI\_ML20684 973-235-5000

Contact: or 800-526-6367 (FOR US ONLY)

### **Locations**

#### **Turkey**

**Not yet recruiting**

ISTANBUL, Turkey, 34300

**Not yet recruiting**

IZMIR, Turkey, 35100

**Recruiting**

ANKARA, Turkey, 06100

**Not yet recruiting**

ANKARA, Turkey, 06018

### **Sponsors and Collaborators**

**Hoffmann-La Roche**

### **Investigators**

Study Director: Clinical Trials Hoffmann-La Roche, +1 973 235 5000

## ▶ **More Information**

Study ID Numbers: ML20684  
First Received: July 17, 2007  
Last Updated: December 18, 2007

ClinicalTrials.gov Identifier: [NCT00502736](#)  
Health Authority: Turkey: Ministry of Health

Study placed in the following topic categories:

Signs and Symptoms	Connective Tissue Diseases
Pathologic Processes	Neoplasm Metastasis
Ibandronic acid	Breast Neoplasms
Skin Diseases	Pain
Bone Neoplasms	Bone Diseases
Bone neoplasms	Breast Diseases

Additional relevant MeSH terms:

Skin and Connective Tissue Diseases	Physiological Effects of Drugs
Neoplastic Processes	Bone Density Conservation Agents
Neoplasms	Pharmacologic Actions
Neoplasms by Site	Pathological Conditions, Signs and Symptoms
Musculoskeletal Diseases	

ClinicalTrials.gov processed this record on January 09, 2008

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