

Study 2 of 55 for search of: Turkey | Phase I II

[← Previous Study](#) [Return to Search Results](#) [Next Study →](#)

[Full Text View](#)

[Tabular View](#)

[Contacts and Locations](#)

[Related Studies](#)

Efficacy and Safety of Tiotropium and Salmeterol in Moderate Persistent Asthma Patients Homozygous for B16-Arg/Arg

This study is currently recruiting participants.

Verified by Boehringer Ingelheim Pharmaceuticals, December 2007

Sponsored by:	Boehringer Ingelheim Pharmaceuticals
Information provided by:	Boehringer Ingelheim Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00350207

► Purpose

This is a 16 week multicentre, multinational, randomised, double-blind, double-dummy, placebo-controlled, parallel group study to evaluate the long-term efficacy and safety of tiotropium compared to salmeterol in moderate persistent asthmatic (GINA step 3) patients homozygous for arginine at the 16th amino acid position of the beta-adrenergic receptor (ADRB2). Following an initial 4-week run-in period on salmeterol MDI patients will be randomised into the 16 week double-blind treatment period in which they receive either tiotropium once daily administered from the Respimat inhaler or salmeterol twice daily administered from the HFA-MDI, or placebo twice daily. After the 16 week treatment period all patients will receive salmeterol MDI twice daily for four weeks. The patients perform daily morning and evening peak flow and FEV1 measurements with an electronic peak flow meter throughout the study. Daily data on asthma control and use of rescue medication are recorded using an electronic diary included in the electronic peak flow meter. On study visits the Mini-Asthma Quality of Life Questionnaire (Elizabeth Juniper) is administered, pulse and blood pressure and pre-dose pulmonary function testing (FEV1 and FVC) is performed.



Condition	Intervention	Phase
Asthma	Drug: Tiotropium bromide Drug: Placebo Drug: Salmeterol xinafoate	Phase II

[MedlinePlus](#) related topics: [Asthma](#)

[ChemIDplus](#) related topics: [Tiotropium](#) [Salmeterol](#) [HFA 227](#)

[U.S. FDA Resources](#)

Study Type: Interventional

Study Design: Treatment, Randomized, Double-Blind, Placebo Control, Parallel Assignment

Official Title: A 16-Week Randomised, Placebo-Controlled, Double-Blind, Double-Dummy, Parallel-Group Study Comparing the Efficacy and Safety of Tiotropium Inhalation Solution Delivered by the Respimat? Inhaler (2 Actuations of 2.5 ?g Once Daily) With That of Salmeterol From the Hydrofluoroalkane Metered Dose Inhale

Further study details as provided by Boehringer Ingelheim Pharmaceuticals:

Primary Outcome Measures:

- The primary endpoint of this study is the change in mean weekly morning peak expiratory flow from baseline to the last week of treatment. Baseline is defined as the last week prior to randomisation visit.

Secondary Outcome Measures:

- Daily morning and evening peak expiratory flow and FEV1 Daily diary on asthma control Morning pre-dose FEV1 and morning pre-dose FVC on study visits Mini-Asthma Quality of Life Questionnaire on study visits adverse events

Estimated Enrollment: 360

Estimated Study Completion Date: January 2008

Eligibility

Ages Eligible for Study: 18 Years to 65 Years

Genders Eligible for Study: Both

Criteria

Inclusion_Criteria:

1. Patients homozygous for arginine at the 16th amino acid position of the beta2 adrenergic receptor (B16 Arg/Arg)
2. All patients must sign and date an Informed Consent Form for the study prior to participation in the trial
3. Male or female outpatients with at least 18 years of age, but not older than 65 years
4. Patients must have a documented history of asthma
5. Patients must be current non-smokers or ex-smokers with a cigarette smoking history of <10 pack-years
6. Patients must be on a maintenance treatment with inhaled corticosteroids with a total daily dose of 400 - 1000 mcg budesonide or equivalent

Exclusion_Criteria:

1. Patients with a significant disease other than asthma
2. Patients with a recent history (i.e., six months or less) of myocardial infarction
3. Patients who have been hospitalized for heart failure (NYHA class III or IV) within the past year
4. Patients with any unstable or life threatening cardiac arrhythmia or cardiac arrhythmia requiring intervention or a change in drug therapy within the past year
5. Patients with malignancy for which the patient has undergone resection, radiation therapy or chemotherapy within the last five years. Patients with treated basal cell carcinoma are allowed.
6. Patients with a diagnosis of chronic obstructive pulmonary disease (COPD)
7. Patients with a history of life threatening pulmonary obstruction, or a history of cystic fibrosis or clinically evident bronchiectasis
8. Patients with known active tuberculosis
9. Patients who have undergone thoracotomy with pulmonary resection.
10. Patients who have completed a pulmonary rehabilitation program in the six weeks prior to visit 1 or patients who are currently in a pulmonary rehabilitation program that will not be maintained throughout the duration of the study.

▶ **Contacts and Locations**

Please refer to this study by its ClinicalTrials.gov identifier: NCT00350207

Contacts

Contact: Boehringer Ingelheim Study Coordinator clintriage@rdg.boehringer-ingelheim.com

Hide Study Locations

Locations

Austria

Boehringer Ingelheim Investigational Site Wien, Austria	Recruiting
Boehringer Ingelheim Investigational Site Graz, Austria	Recruiting
Boehringer Ingelheim Investigational Site Wels, Austria	Recruiting
Boehringer Ingelheim Investigational Site Trofaiach, Austria	Recruiting
Boehringer Ingelheim Investigational Site Wien, Austria	Not yet recruiting
Belgium	
Boehringer Ingelheim Investigational Site Gent, Belgium	Recruiting
Boehringer Ingelheim Investigational Site Bruxelles, Belgium	Recruiting
Boehringer Ingelheim Investigational Site Herentals, Belgium	Recruiting
Boehringer Ingelheim Investigational Site Malmedy, Belgium	Recruiting
Boehringer Ingelheim Investigational Site Angleur, Belgium	Recruiting
Boehringer Ingelheim Investigational Site Montigny-le-Tilleul, Belgium	Recruiting
Boehringer Ingelheim Investigational Site Brussel, Belgium	Recruiting
Boehringer Ingelheim Investigational Site Namur, Belgium	Recruiting
Boehringer Ingelheim Investigational Site Anderlecht, Belgium	Recruiting
Boehringer Ingelheim Investigational Site Turnhout, Belgium	Recruiting
Boehringer Ingelheim Investigational Site Menen, Belgium	Recruiting
Boehringer Ingelheim Investigational Site	Recruiting

Yvoir, Belgium

Denmark

Boehringer Ingelheim Investigational Site Hvidovre, Denmark	Recruiting
Boehringer Ingelheim Investigational Site K?benhavn NV, Denmark	Recruiting
Boehringer Ingelheim Investigational Site Aalborg, Denmark	Recruiting
Boehringer Ingelheim Investigational Site Odense C, Denmark	Recruiting

Finland

Boehringer Ingelheim Investigational Site Jyvaskyla, Finland	Recruiting
Boehringer Ingelheim Investigational Site Lahti, Finland	Recruiting
Boehringer Ingelheim Investigational Site Helsinki, Finland	Recruiting
Boehringer Ingelheim Investigational Site Tampere, Finland	Recruiting

France

UCP-X - Clinique Medicale Grenoble, France	Recruiting
Hopital Arnaud de Villeneuve Montpellier, France	Recruiting
CLEFAR - Clinique de la Louviere Lille Cedex, France	Recruiting
Clinique de la Louviere Lille, France	Recruiting
CLEFAR - Clinique de la Louviere Lille, France	Recruiting
Boehringer Ingelheim Investigational Site Chamalieres, France	Recruiting
Centre Hosp de la Cavale Blanche	Recruiting

Brest, France	
MEDISCIS	Recruiting
Poitiers, France	
Boehringer Ingelheim Investigational Site	Recruiting
Chauny, France	
Boehringer Ingelheim Investigational Site	Recruiting
Saint Pierre la Reunion, France	
Germany	
Boehringer Ingelheim Investigational Site	Recruiting
Weinheim, Germany	
Boehringer Ingelheim Investigational Site	Recruiting
Bruchsal, Germany	
Boehringer Ingelheim Investigational Site	Recruiting
Berlin, Germany	
Boehringer Ingelheim Investigational Site	Recruiting
Rudersdorf, Germany	
Boehringer Ingelheim Investigational Site	Recruiting
Kassel, Germany	
Boehringer Ingelheim Investigational Site	Recruiting
Minden, Germany	
Boehringer Ingelheim Investigational Site	Recruiting
Koln, Germany	
Boehringer Ingelheim Investigational Site	Recruiting
Mainz, Germany	
Boehringer Ingelheim Investigational Site	Recruiting
Frankfurt/Main, Germany	
Boehringer Ingelheim Investigational Site	Recruiting
Rathenow, Germany	
Boehringer Ingelheim Investigational Site	Recruiting
Neuruppin, Germany	
Boehringer Ingelheim Investigational Site	Recruiting
Beelitz-Heilstatten, Germany	

Greece

Boehringer Ingelheim Investigational Site Athens, Greece	Recruiting
Boehringer Ingelheim Investigational Site Thessaloniki, Greece	Recruiting
Boehringer Ingelheim Investigational Site Larisa, Greece	Recruiting
Boehringer Ingelheim Investigational Site Heraklion, Greece	Recruiting
Boehringer Ingelheim Investigational Site Kavala, Greece	Recruiting
Italy	
Ospedale di Cisanello PISA, Italy	Recruiting
Universita di Modena e Reggio Emilia MODENA, Italy	Recruiting
Azienda Ospedaliera " S. Anna" FERRARA, Italy	Recruiting
Boehringer Ingelheim Investigational Site ORBASSANO (TO), Italy	Recruiting
Azienda Ospedaliera Universitaria Careggi FIRENZE, Italy	Recruiting
Policlinico San Matteo PAVIA, Italy	Recruiting
Boehringer Ingelheim Investigational Site MILANO, Italy	Not yet recruiting
Boehringer Ingelheim Investigational Site SESTO SAN GIOVANNI (MI), Italy	Not yet recruiting
Ospedale San Martino GENOVA, Italy	Recruiting
Russian Federation	
Boehringer Ingelheim Investigational Site Moscow, Russian Federation	Recruiting
Boehringer Ingelheim Investigational Site	Recruiting

St. Petersburg, Russian Federation

Slovakia

Boehringer Ingelheim Investigational Site Banska Bystrica, Slovakia	Recruiting
Boehringer Ingelheim Investigational Site Bratislava, Slovakia	Recruiting
Boehringer Ingelheim Investigational Site Kosice, Slovakia	Recruiting
Boehringer Ingelheim Investigational Site Trencin, Slovakia	Recruiting
Boehringer Ingelheim Investigational Site Zilina, Slovakia	Recruiting

South Africa

Boehringer Ingelheim Investigational Site Cape Town, South Africa	Recruiting
Boehringer Ingelheim Investigational Site Bellville, South Africa	Recruiting
Boehringer Ingelheim Investigational Site Durban, South Africa	Recruiting
Boehringer Ingelheim Investigational Site Pretoria, South Africa	Recruiting
Boehringer Ingelheim Investigational Site Centurion, South Africa	Recruiting
Boehringer Ingelheim Investigational Site George, South Africa	Recruiting
Boehringer Ingelheim Investigational Site Bloemfontein, South Africa	Recruiting

Spain

Hospital de Gran Canaria Dr. Negrin Las Palmas de Gran Canaria, Spain	Recruiting
Hospital Universitario La Paz Madrid, Spain	Recruiting
Hospital General Universitario de Guadalajara	Recruiting

Guadalajara, Spain Hospital Virgen de la Macarena Sevilla, Spain	Recruiting
Boehringer Ingelheim Investigational Site Centelles, Spain	Not yet recruiting
Hospital Universitari Arnau de Vilanova Lleida, Spain	Recruiting
Hospital Universitario Marques de Valdecilla Santander, Spain	Recruiting
Hospital Universio Puerta del Hierro Madrid, Spain	Recruiting
Hospital General Universitario de Valencia Valencia, Spain	Recruiting
Hospital Clinic i Provincial de Barcelona Barcelona, Spain	Recruiting
Turkey	
Boehringer Ingelheim Investigational Site Ankara, Turkey	Recruiting
Ege Universitesi Tip Fakultesi Gogus Hastalıkları A.B.D. Izmir, Turkey	Recruiting
Boehringer Ingelheim Investigational Site BURSA, Turkey	Recruiting
Celal Bayar Universitesi Tip Fakultesi Manisa, Turkey	Not yet recruiting
Kocaeli Universitesi Tip Fakultesi Izmit, Turkey	Recruiting
Istanbul Universitesi Cerrahpasa Tip Fakultesi Istanbul, Turkey	Recruiting
United Kingdom	
Boehringer Ingelheim Investigational Site Leicester, United Kingdom	Recruiting
Boehringer Ingelheim Investigational Site Aylesbury, United Kingdom	Recruiting

Boehringer Ingelheim Investigational Site Greenisland, United Kingdom	Recruiting
Boehringer Ingelheim Investigational Site Boscastle, United Kingdom	Recruiting
Boehringer Ingelheim Investigational Site Nottingham, United Kingdom	Recruiting
Boehringer Ingelheim Investigational Site Chertsey, United Kingdom	Recruiting

Sponsors and Collaborators

Boehringer Ingelheim Pharmaceuticals

Investigators

Study Chair: Boehringer Ingelheim Study Coordinator Boehringer Ingelheim Pharmaceuticals

 **More Information**

Study ID Numbers: 205.342
 First Received: July 7, 2006
 Last Updated: December 18, 2007
 ClinicalTrials.gov Identifier: [NCT00350207](http://www.clinicaltrials.gov/ct2/show/study/NCT00350207)
 Health Authority: United States: Food and Drug Administration

Study placed in the following topic categories:

Hypersensitivity	Hypersensitivity, Immediate
Lung Diseases, Obstructive	Asthma
Salmeterol	Tiotropium
Bromides	Respiratory Hypersensitivity
Lung Diseases	

Additional relevant MeSH terms:

Parasympatholytics	Cholinergic Agents
Respiratory System Agents	Adrenergic Agonists
Neurotransmitter Agents	Molecular Mechanisms of Action
Cholinergic Antagonists	Pharmacologic Actions
Bronchial Diseases	Respiratory Tract Diseases
Immune System Diseases	Autonomic Agents
Adrenergic beta-Agonists	Therapeutic Uses

Adrenergic Agents
Physiological Effects of Drugs
Anti-Asthmatic Agents

Peripheral Nervous System Agents
Bronchodilator Agents

ClinicalTrials.gov processed this record on January 09, 2008

[U.S. National Library of Medicine](#), [Contact Help Desk](#)
[U.S. National Institutes of Health](#), [U.S. Department of Health & Human Services](#),
[USA.gov](#), [Copyright](#), [Privacy](#), [Accessibility](#), [Freedom of Information Act](#)

