ISRCTN14703590 https://doi.org/10.1186/ISRCTN14703590

The effect of a Bacterial Extract on Asthma Control (BEAC)

Submission date	Recruitment status	[ ] Prospectively registered
12/03/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/04/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/04/2011	Respiratory	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Antonios Christopoulos

Contact details
157 Mezonos Street
Patras
Greece
262 21

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
007

Study information

Scientific Title

The effect of the oral bacterial extract OM-85 BV on asthma control a real life study

Acronym
BEAC

Study objectives
Evaluating the additive effect of oral OM-85 BV, Bronho-Vaxom OM Pharma, Geneva, Switzerland), to the combination of inhaled glucocorticosteroids (ICS) plus long-acting beta 2-agonist (LABA), upon the level of asthma control in young adolescents and adult patients.
Our hypothesis was that OM-85 BV would provide additional benefit, as measured by the proportion of patients who would achieve control of their asthma in the lowest step and dose of treatment necessary.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of Patras Reference number 443 from 15.05/004.
2. University of Patras, School of Health Sciences, Greece - Program of Postgraduated Studies in Clinical & Clinical-Laboratory Specialties which function under the Ministerial decision Β7/458 π.ε /8.2.02, ΦΕΚ 191/20.2.02, as part of the MSc Thesis 443/17.5.04

Study design
Randomized double blind parallel group prospective study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Atopy associated mild to moderate bronchial asthma

Interventions
1. Eligible patients received non-blinded the appropriate maintenance treatment (inhaled budesonide 200-800 μg/day plus formoterol 18mcg/day, administered twice daily).
2. The selection of the budesonide dosage was determined by the patients level of asthma control and the treatment already commenced
3. Patients were inhaled budesonide and formoterol from a Turbohaler (Pulmicort 200μg and Oxez 9μg respectively, AstraZeneca Liquid Production, Sweden)

4. During the last 2 weeks of this period, single blind placebo OM-85 BV (saccharin) was added
5. In the end of the run-in period patients were reassessed to establish their adherence to the current regimen and level of asthma control. Following, eligible patients were randomized in three strata: Stratum I (uncontrolled, NCA), stratum 2 (partly controlled asthma, PCA) and stratum 3 (controlled asthma, CA).
6. In NCA patients the dose of budesonide was stepped up to 4 times the dose used (up to 1600 μg/day)
7. In PCA patients the dose of budesonide was increased by 50%, while in CA patients budesonide dosage was stepped down by 50%.
8. Following patients in each stratum were randomized according to a central computer generated schedule, to receive either 7mg of OM-85 BV (Bronho-Vaxom; OM PHARMA;Geneva; Switzerland)) or matching placebo saccharin once daily, orally, fasting in the morning
9. Treatment assignments (1:1) were stratified in every stratum according 3 budesonide dose levels (200-400, 400-800 and 800-1600 mcg/day)
10. In the absence of exacerbations and/or adverse events, patients were reassessed every 12 weeks and the dose of budesonide was titrated each time, as prescribed above.
11. During the study, use of theophylline, leukotriene modifiers and extra formoterol was not permitted
12. Nedocromyl nasal spray and eye drops were permitted, in order to treat allergic rhinitis and conjunctivitis respectively
13. The study consistent of two treatment periods: a 4 week run-in and a 24 week double blind
14. Lung Function Tests (spirometry), Skin Prick Tests for aero-allergens and 2 blood samples (1+1 ml) for serum interferon- γ (INF-γ) measurements

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
OM-85 BV - a bacterial extract

Primary outcome measure
The percentage of patients with:
1. Non Controlled Asthma
2. Partly Controlled Asthma
3. Controlled Asthma in every stratum, in the two treatment groups, at the end of the active treatment period

Secondary outcome measures
1. Percentage change from baseline in budesonide dosage
2. Mean FEV1 before using a beta 2 agonist
3. Mean PEF, diurnal variability of peak expiratory flow (PEF)
4. Daytime asthma symptoms score
5. Number of night awakenings
6. Total daily as-needed β2 agonist use and serum interferon- γ (INF- γ) levels

Overall study start date
01/10/2010

Completion date
30/04/2011

Eligibility

Key inclusion criteria
1. Patients were aged 15-57 years and had a history of persistent asthma for a year or longer, associated with allergy
2. All patients were in regular treatment with combinations of ICS plus LABA, for at least 8 weeks before entering the study
3. Enrolled patients had a Forced Expiratory Volume in one second (FEV1) 60% to 80% of predicted normal, at least 12% reversible to inhaled salbutamol and 15% to 30% diurnal change of Peak Expiratory Flow (PEF)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Above 100 patients

Key exclusion criteria
1. Smoking history of ≥ 10 pack per year and systemic use of corticosteroids
2. Patients with a respiratory tract infection affecting asthma and those who received oral or parental corticosteroids during the 4 week run-in period, chromones, leukotriene receptor antagonists or inhaled anticholinergics during the last 2 weeks, and theophylline or antihistamines during the last week of the run in period were not eligible for randomization 3. As variations in the exposure to domestic mite allergens have a significant impact on asthma related symptoms, patients with history and/or positive skin prick tests for indoor allergens were not included to the study

Date of first enrolment
01/10/2010

Date of final enrolment
30/04/2011

Locations

Countries of recruitment
Greece

Study participating centre

157 Mezonos Street
Patras
Greece
262 21

Sponsor information

Organisation
University of Patras (Greece)

Sponsor details
Faculty of Medicine
University of Patras
Patras
Greece
265 00

Sponsor type
University/education

Website
http://www.med.upatras.gr

ROR
https://ror.org/017wvtq80

Funder(s)

Funder type
University/education

Funder Name
University of Patras (Greece)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration