ISRCTN31998214 https://doi.org/10.1186/ISRCTN31998214

Utilization of the Asthma Control Test at the initiation of therapy for patients with asthma

Submission date
06/09/2011

Recruitment status
No longer recruiting

Registration date
21/09/2011

Overall study status
Completed

Last Edited
21/04/2017

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Asthma is a common lung condition that causes occasional breathing difficulties. The Asthma Control Test provides asthma sufferers and their doctors and nurses with a score to help them determine the level of treatment required. The aim of this study is to assess the responsiveness of the Asthma Control Test to detect changes in patients' clinical status at the start of treatment in a primary care (GP) setting.

Who can participate?
Patients aged over 12 with asthma

What does the study involve?
At the first visit, a nurse performs basic vital signs screening, measures breathing, completes a data collection form (disease duration, education level, breathing symptoms, smoking), and asks the participant to complete the Asthma Control Test. Participants are then randomly allocated to receive their initial treatment based on either the Saudi Initiative for Asthma (SINA) approach or the Global Initiative for Asthma (GINA) approach. The recommended steps of asthma treatment are as follows:
Step 1: rapid onset B2 agonist (reliever) inhaler as needed
Step 2: low doses inhaled corticosteroids (preventer inhaler)
Step 3: low-medium dose inhaled corticosteroids with long-acting bronchodilator (long-acting reliever inhaler)
Participants in the SINA group receive their initial treatment based on the result of the Asthma Control Test, starting at step 1 when the score is 20 or over, step 2 when the score is 16-19, and step 3 when the score is less than 16. The GINA group patients start on step 2 when they have persistent asthma symptoms or step 3 when they have severely uncontrolled disease. Patients receive an education session explaining the nature of asthma, the importance of compliance with treatment, the features of an asthma attack, and inhaler technique. A follow-up visit is offered to the patients 4 weeks later to assess their level of asthma control using the Asthma Control Test. Between the visits, participants are advised to visit their doctor or the emergency department if they feel that their asthma is not controlled.

What are the possible benefits and risks of participating?
Patients will receive standard treatment, close follow-up and education. There are no known side effects of taking part in the study.

Where is the study run from?
King Abdullah International Medical Research Center (Saudi Arabia)

When is the study starting and how long is it expected to run for?
September to October 2011

Who is funding the study?
King Abdullah International Medical Research Center (Saudi Arabia)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
RC10/091

Study information

Scientific Title
Utilization of the Asthma Control Test at the initiation of therapy for patients with asthma: a randomized controlled trial

Acronym
UACTA

Study objectives

The global initiative for asthma have hypothesized that initiation of asthma therapy is based on physician judgment. We challenged that by utilizing the asthma control test at the initiation of therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
King Abdullah International Medical Research Center, 05/03/2011

Primary study design
Interventional

Study design
Randomized clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Asthma

Interventions
Patients will be randomized to receive their initial treatment based on either the Saudi Initiative for Asthma (SINA) Approach (Group A) or the Global Initiative for Asthma (GINA) approach (group B).

At the initial visit, the nurse will perform the basic vital signs screening, measures forced expiratory volumes in one second (FEV1) and peak expiratory flow, fill the data collection form (Disease duration, education level, respiratory symptoms, exacerbation and admissions, smoking, and pulmonary function tests), and ask the patients to fill the baseline ACT. Patients will be assigned to either group A or B, based on a simple random allocation. Randomization will be carried out by a biostatistician, and the allocation treatment will be concealed in a closed opaque envelope.

The primary care physicians will be trained by the authors to either the SINA or GINA approach. Those who will follow the SINA approach will base their initial treatment on the result of ACT where they will receive treatment at step 1,2, or 3. While those patients allocated to group B will be commenced on step 2 based on GINA when they have persistent asthma symptoms and step 3 when they have severely uncontrolled disease. Patients will receive an education session for their asthma that consist of: explaining the nature of disease, importance of compliance, features of asthma attack, and inhalers technique.

Step1: Rapid onset B2 agonist inhaler on as needed bases.
Step 2: Inhaled corticosteroids low doses.
Step 3: Low-medium dose inhaled corticosteroids with long acting bronchodilator.

A follow-up visit will be offered to the patients 4 weeks later to assess their level of asthma control by ACT. Between the visits, patients will be advised to come back for their physicians or visit Emergency department if they feel that their asthma is not controlled.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Step up or down of therapy
2. Change in asthma control test (ACT)
3. Change in peak expiratory flow (PEF)
Measured at initiation visit then follow-up visit in 4 weeks time

Key secondary outcome(s)
Change in forced expiratory volume in 1 sec (FEV1), measured at initiation visit then follow-up visit in 4 weeks time

Completion date
25/10/2011

Eligibility

Key inclusion criteria
1. Age above 12 years with the diagnosis of asthma
2. Literate patient
3. No controller therapy for 2 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
Use of controller therapy for 2 months

Date of first enrolment
10/09/2011

Date of final enrolment
25/10/2011

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
PO Box 84252
Riyadh
Saudi Arabia
11671

Sponsor information

Organisation
King Abdullah International Medical Research Center (Saudi Arabia)

ROR
https://ror.org/009p8zv69

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
King Abdullah International Medical Research Center (Saudi Arabia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/03/2012		Yes	No