

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

<b>Submission date</b> 06/09/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/09/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/04/2017	<b>Condition category</b> Respiratory	<input type="checkbox"/> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

**Study design**

Randomized clinical trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

GP practice

**Study type(s)**

Treatment

**Participant information sheet**

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

**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 measure**

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

### **Secondary outcome measures**

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

### **Overall study start date**

10/09/2011

### **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

### **Age group**

Mixed

### **Sex**

Both

**Target number of participants**

45-50 patients in each arm i.e., GINA arm and SINA arm

**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**

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## **Sponsor information**

**Organisation**

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.kaimrc.med.sa/>

ROR

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

King Abdullah International Medical Research Center (Saudi Arabia)

## 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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	26/03/2012		Yes	No