

This document provides a short summary of this study for a general audience. You can find more information in the scientific summary of the study. A link to the summary is provided at the end of this document.

Study names

Short Title: A study to compare treatment guided by the Asthma Control Test with usual treatment in Chinese patients.

Full Scientific Title: The effectiveness of Asthma Control Test guided treatment compared with usual care in China adult asthma patients.

Study Number: 201097

Who sponsored this study?

GlaxoSmithKline (GSK)

GSK Clinical Support Help Desk

Website: clinicalsupporthd.gsk.com/contact.html

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General information about the clinical study

When and where was this study done?

The study started in August 2016 and ended in August 2019. All study sites were in China.

What was the main objective of this study?

Asthma is a long-term condition of the airways. When the airways are inflamed, they become narrow. This narrowing can cause coughing, wheezing, chest tightness, and shortness of breath.

Simple methods have been developed to help doctors assess asthma control in patients. One of these methods is the Asthma Control Test (ACT), which is a short survey. The ACT was designed to measure how well a patient's asthma has been

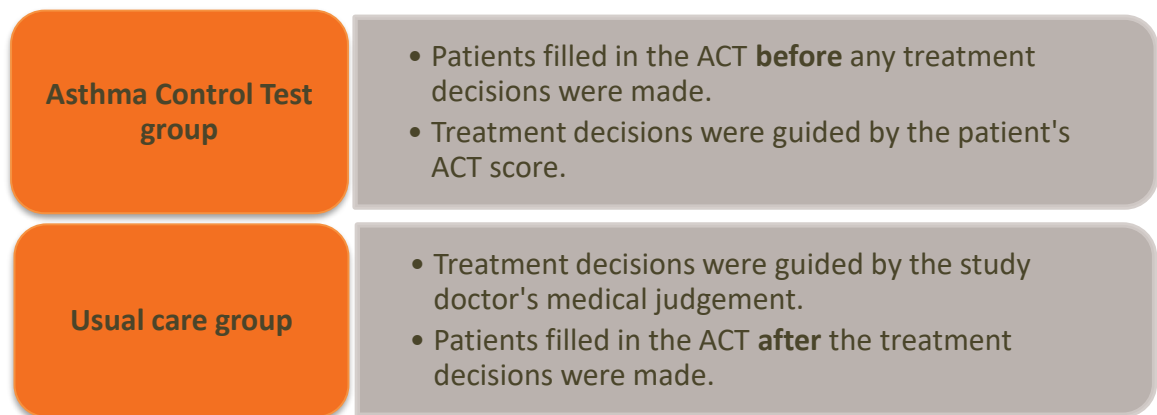
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controlled and guide doctors' treatment decisions. Doctors in China do not routinely use the ACT.

The main objective of this study was to compare treatment decisions guided by patients' ACT scores with treatment decisions guided by doctors' medical judgement (usual care) in Chinese patients.

What was studied?

Clinics in China providing asthma care were selected for the study. These clinics were classified into two study groups (see figure below). Patients knew which study group they were assigned to and which treatment they received. This is called an open-label study. Treatment prescribed to patients during the study could include GSK and/or non-GSK medicine(s).



Every morning and evening, patients recorded their symptoms and the medicines that they took in a diary card. Patients visited their assigned clinic every four weeks during the 24-week study period. At each visit, patients completed the ACT. They scored their asthma symptoms over the previous four weeks. ACT scores range from 5 to 25. Patients with higher scores have better asthma control.

Which patients were included in this study?

Studies have a list of requirements for patients who can enrol (inclusion criteria) and those who can't (exclusion criteria). For this study, the main inclusion and exclusion criteria are listed below.



Men and women with asthma were included in the study if they:

- Were between 18 to 70 years of age.
- Had history of asthma for at least six months before starting the study.
- Were taking an inhaled corticosteroid (a medicine that reduces inflammation in the lungs) alone or in combination with an inhaled long-acting beta agonist (a medicine that helps relax and open the airways) within one year before starting the study.
- Had ACT score of less than 20 at the start of the study.



Men and women were excluded from the study if they had:

- A history of life-threatening asthma that required hospitalisation within six months before starting the study.
- Severe and unstable asthma within six weeks before starting the study.
- Infection of the respiratory tract within four weeks before starting the study.
- Other respiratory diseases such as tuberculosis, lung cancer, or chronic obstructive pulmonary disease.
- Current or former heavy smokers.
- Any other disease(s) or had taken any medicines in six weeks before starting the study, that the study doctor thought would affect the results of the study.

The study included 507 patients who had their results assessed: 257 (51%) men and 250 (49%) women. The average age was 48 years. The youngest patient was 18 years old and the oldest patient was 73 years old.

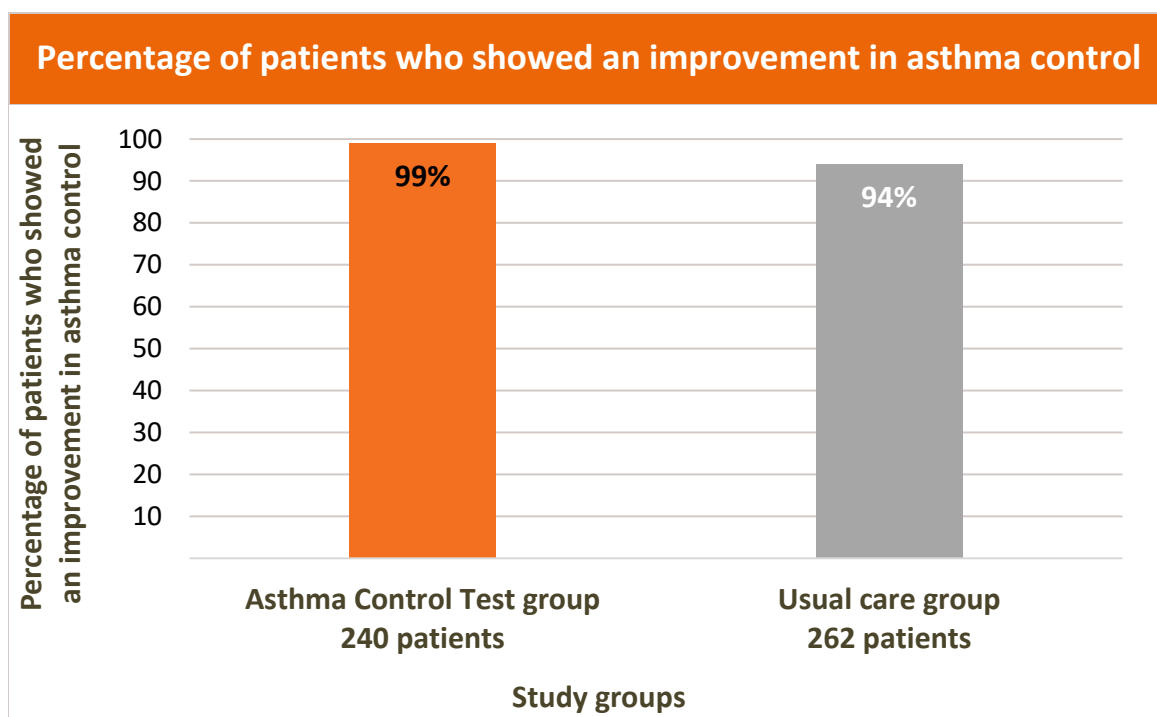
For more detailed information about the patients included in this study, see the scientific results summary (a link to the summary is provided at the end of this document).

What were the overall results of the study?

The main focus of the study was to see the percentage of patients who showed an improvement in asthma control. Patients were considered to have shown an improvement in asthma control if:

- their ACT score was 20 or more during the study
- OR
- their ACT score during the study was more than three points higher than their ACT score at the start of the study (baseline).

Improvement in asthma control was calculated for 502 patients who had a baseline ACT score and at least one ACT score recorded during the study. The percentage of patients who showed an improvement in asthma control are shown in the figure below.



The majority of patients in both study groups had improvement in asthma control. The percentage of patients who showed an improvement in their asthma control was higher in the Asthma Control Test group compared with the usual care group.

More information about the study results is available in the scientific results summary (a link to the summary is provided at the end of this document).

What were the side effects?

Unwanted medical events (adverse events) can happen to people when they receive a medicine. Study doctors record these events. A summary of all these events can be found in the scientific results summary (a link to the summary is provided at the end of this document).

If the study doctor thinks that the event was caused by the treatment (medicine or process), they record this as a possible side effect (adverse reaction).

In this summary, “side effects” refer to those events that the study doctor thinks may have been caused by any of the GSK medicine(s) prescribed to the patient during the study (GSK medicine(s)-related side effects) or by the treatment process (study process-related side effects). The side effects in this summary may be different to those in the Informed Consent or other documents.

A total of 506 patients were included for the side effects summary.

No serious side effects were reported in the study.

No non-serious GSK medicine(s)-related side effects were reported in the Asthma Control Test group. One patient (less than 1%) in the usual care group reported a non-serious GSK medicine(s)-related side effect of rash.

The non-serious study process-related side effects are shown in the table below.

Non-serious study process-related side effects		
	Asthma Control Test group 241 patients	Usual care group 265 patients
Asthma	1 (less than 1%)	0
Cough	1 (less than 1%)	0
Throat irritation	1 (less than 1%)	0
Pain in the mouth and throat	0	1 (less than 1%)

How has this study helped patients and researchers?

Researchers concluded that treatment decisions guided by ACT scores resulted in improved asthma control in Chinese patients compared with usual care. Side effects reported in this study were limited.

Are there plans for further studies?

No further studies on ACT in Chinese patients with asthma have been planned at this time.

Where can I find more information about this study?

Clinical studies have unique a study number that is included in publications and other information about the study. The unique study numbers associated with this study are shown below with an internet link to the scientific summary and other information.

The scientific summary includes more details about the requirements for study enrolment, the study visit schedule, results from other endpoints, and more detailed information about adverse events.

Organisation	Website	Study Number
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT02868281 ¹

Your doctor can help you understand more about this study and the results. Speak to your doctor about the treatment options available in your country. You should not make changes to your care based on the results of this or any single study. Keep taking your current treatment unless instructed by your doctor.

We would like to thank the patients who contributed to this study. The results of this study will help answer scientific questions about treating patients with asthma.

The content for this document was finalised by GSK on the 23rd of March 2020. The information in this summary does not include additional information available after this date.

¹<https://clinicaltrials.gov/ct2/show/NCT02868281>