

# Management of asthma in school-age children on therapy

<b>Submission date</b> 08/11/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/11/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/02/2020	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Asthma is a common long-term condition that can cause coughing, wheezing, chest tightness and breathlessness. It affects 1 in 8 children in the UK. Up to half of these are treated with preventative medicine in the form of low-dose steroids using an inhaler. The National Asthma Treatment Guidelines recommend when this treatment is not working other treatments should be started. Studies to support this have taken place in adults but not with children.

### Who can participate?

Children with asthma aged 6 - 14

### What does the study involve?

If patients are instructed how to use inhalers and are given information about asthma, they can control their disease much better. The first part of this study, lasting 4 weeks, makes sure that the children and their families understand how to use their inhaler. All participating children are given the same steroid inhaler to use and after 4 weeks those still with symptoms enter the study proper which lasts for 48 weeks. During this part of the study the children are randomly allocated to be given one of three treatments: a steroid inhaler and a dummy tablet; an inhaler containing a steroid and a long-acting reliever and a dummy tablet; or a steroid inhaler and an active tablet. What matters to children is how they feel, are they able to run around and play with friends, and are they well enough to go to school. We assess which of the above treatments best allow these to happen by asking the parents and children to fill in questionnaires on four occasions during the study. We also assess which treatment best prevents the need for short courses of steroid tablets during the study. These are commonly given when asthma symptoms worsen.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

North Staffordshire Medical Institute (UK)

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

January 2009 to September 2011

Who is funding the study?

Health Technology Assessment Programme (UK)

Who is the main contact?

Prof. Warren Lenney

## Contact information

### Type(s)

Scientific

### Contact name

Prof Warren Lenney

### Contact details

Research & Development Department  
North Staffordshire Medical Institute  
Hartshill Road  
Hartshill  
Stoke-on-Trent  
United Kingdom  
ST4 7QB

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT01526161

Secondary identifying numbers

HTA 05/503/04

## Study information

### Scientific Title

Management of Asthma in School-age Children On Therapy

### Acronym

MASCOT

### Study objectives

Children whose asthma is uncontrolled on low dose Inhaled Corticosteroids (ICS) will have their control improved by prescribing 'add-on' therapies (long-acting beta-2 agonists and/or leukotriene receptor antagonists) in addition to low dose ICS treatment.

More details can be found at: <http://www.nets.nihr.ac.uk/projects/hta/0550304>

Protocol can be found at: [http://www.nets.nihr.ac.uk/\\_\\_data/assets/pdf\\_file/0013/51223/PRO-05-503-04.pdf](http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0013/51223/PRO-05-503-04.pdf)

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

North West Research Ethics Committee, 03/04/2008, ref: 08/H1010/8

### **Study design**

Prospective controlled double-blind multicentre randomised clinical trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

### **Study type(s)**

Treatment

### **Participant information sheet**

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

### **Health condition(s) or problem(s) studied**

Asthma (paediatric population)

### **Interventions**

1. Inhaled fluticasone propionate 100 µg twice daily plus placebo tablet once daily
2. Inhaled fluticasone propionate 100 µg and salmeterol 50 µg twice daily (combination inhaler) plus placebo tablet once daily
3. Inhaled fluticasone propionate 100 µg twice daily plus montelukast 5 mg tablet once daily

There is a four week run-in period, followed by a 48 week intervention and follow up period (for those patients eligible at randomisation). Patients in the randomised phase will receive study treatment for the full 48 weeks.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Fluticasone propionate, salmeterol, montelukast

### **Primary outcome measure**

The main research objective is to determine, in 6 - 14 year old children with asthma, uncontrolled on low-dose ICS, whether their control can be improved by adding in a long-acting beta-2 agonist (salmeterol) or a leukotriene receptor antagonist (montelukast) as measured by a reduced number of exacerbations requiring treatment with oral corticosteroids over the 48 week study period.

### **Secondary outcome measures**

1. Quality of Life measured by the Juniper QoL questionnaire, collected at baseline, randomisation, then +8 weeks, +24 weeks, +36 weeks and +48 weeks
2. Time from randomisation to first exacerbation requiring treatment with a short course of oral corticosteroids, collected at baseline, randomisation, then +8 weeks, +24 weeks, +36 weeks and +48 weeks
3. School attendance, collected at baseline, randomisation, then +8 weeks, +24 weeks, +36 weeks and +48 weeks
4. Hospital admissions, collected at baseline, randomisation, then +8 weeks, +24 weeks, +36 weeks and +48 weeks
5. Amount of rescue beta-2 agonist therapy prescribed, collected at baseline, randomisation, then +8 weeks, +24 weeks, +36 weeks and +48 weeks
6. Time from randomisation to treatment withdrawal (due to lack of efficacy or side effects), collected at baseline, randomisation, then +8 weeks, +24 weeks, +36 weeks and +48 weeks
7. Lung function (as assessed by spirometry), conducted at baseline/randomisation (T0) and randomisation + 48 weeks (T48)

### **Overall study start date**

01/01/2009

### **Completion date**

30/09/2011

## **Eligibility**

### **Key inclusion criteria**

1. Children with physician diagnosed asthma aged 6 years - 14 years 11 months
2. Those requiring frequent short-acting beta-2 agonist relief therapy greater than or equal to 7 puffs per week
3. Those with symptoms of asthma (i.e. wheeze, shortness of breath but not cough) resulting in:
  - 3.1. Difficulty sleeping in the last week because of asthma symptoms and/or
  - 3.2. Asthma has interfered with usual activities in the last week and/or
  - 3.3. Those who have had exacerbations, defined as a short course of oral corticosteroids, an unscheduled General Practitioner (GP) or Accident and Emergency (A&E) Department visit or a hospital admission within the previous 6 months
4. Fully informed consent written (proxy) consent and assent, where appropriate

### **Participant type(s)**

Patient

### **Age group**

Child

**Lower age limit**

6 Years

**Upper age limit**

14 Years

**Sex**

Both

**Target number of participants**

900

**Key exclusion criteria**

1. Children receiving long acting beta-2-agonists, leukotriene receptor antagonists, regular theophylline therapy or high dose ICS
2. Children with other respiratory diseases, cystic fibrosis, cardiac disease or immunological disorders

**Date of first enrolment**

01/01/2009

**Date of final enrolment**

30/09/2011

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

North Staffordshire Medical Institute

Stoke-on-Trent

United Kingdom

ST4 7QB

**Sponsor information****Organisation**

University Hospital of North Staffordshire NHS Trust (UK)

**Sponsor details**

Research & Development Department

North Staffordshire Medical Institute

Hartshill Road  
Hartshill  
Stoke-on-Trent  
Staffordshire  
England  
United Kingdom  
ST4 7QB

**Sponsor type**

Hospital/treatment centre

**Organisation**

Keele University (UK)

**Sponsor details**

Research Services  
Room DH 1.13, Dorothy Hodgkin Building  
Keele  
England  
United Kingdom  
ST5 5BG  
+44 (0)1782 583 374  
j.m.garside@uso.keele.ac.uk

**Sponsor type**

University/education

**Website**

[www.keele.ac.uk](http://www.keele.ac.uk)

**Organisation**

University Hospital of North Staffordshire NHS Trust

**Sponsor details**

**Sponsor type**

Not defined

**Website**

<https://www.nhs.uk/Services/Trusts/Overview/DefaultView.aspx?id=1471>

**Funder(s)**

**Funder type**

Government

**Funder Name**

Health Technology Assessment Programme

**Alternative Name(s)**

NIHR Health Technology Assessment Programme, HTA

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## 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	01/02/2013		Yes	No