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Management of asthma in school-age children on therapy

Submission date	Recruitment status	[X] Prospectively registered
08/11/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/11/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/02/2020	Respiratory	

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

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

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?
Results article	results	01/02/2013		Yes	No