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FAST - four-fold asthma study: the clinical and cost effectiveness of temporarily quadrupling the dose of inhaled steroid to prevent asthma exacerbations

Submission date
25/04/2013

Recruitment status
No longer recruiting

Registration date
25/04/2013

Overall study status
Completed

Last Edited
11/12/2018

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Many people with asthma take regular inhaled steroids. These are either given alone or as part of a combination treatment. Despite regular treatment with inhaled steroids, some patients continue to have periods of poor asthma control, which are called exacerbations. Exacerbations often require treatment with steroid tablets and can lead to time away from school or work. Previous asthma guidelines have advised patients to double their dose of inhaled steroid at the first sign of a cold or worsening asthma symptoms, which has been shown not to work. A recent study has shown that increasing the dose to four times the normal dose for a short time may help in preventing an exacerbation but this is not certain. This study would like to test this by comparing a modified self-management plan to the one used in clinical care at the moment. This modified plan recommends taking four times the normal dose of inhaled corticosteroid when participant's asthma control starts to get worse.

Who can participate?
Men and women age 16 and over who have asthma and have been prescribed an inhaled steroid

What does the study involve?
If patients are interested in taking part, an appointment is made for them to visit the clinic, where they can have a chat about the study and answer any questions. If patients are still interested in taking part they need to sign a consent form and then some details are recorded about them. Participants also be asked to complete three short questionnaires and have their peak flow (maximum speed of expiration) measured. To find out which self-management plan is best and to avoid any bias, participants are not able to choose which plan they receive, instead they are allocated one of the two plans (asthma self-management plan which includes an increase in inhaled corticosteroid or the same plan without an increase in inhaled corticosteroid) by chance. The self-management plan advises participants what to do if their asthma gets worse. Participants also receive a diary card and training about how and when to complete this. At some sites, participants may be asked if they can attach an electronic device to one of their inhalers to

count how many puffs of the inhaler they take. Participants need to come back to the clinic at 6 and 12 months after they start the study. During these visits the study team review and discuss their asthma self-management plan and participants are asked to complete several short questionnaires asking about their quality of life and use of NHS services. This should take no longer than 45 minutes. In addition, if the participant's asthma starts to get worse during the study and they move into Zone 2 of their self-management plan, participants need to start to complete the diary card and to make an appointment to come into the clinic 14 days later. At this visit a member of the research team reviews their diary card and discusses their asthma self-management plan. Participants are also asked to complete a short quality of life questionnaire. The research team sends a text message to the participants every month to remind them about their self-management plan. Participants remain on their own regular asthma medication throughout the study as part of their self-management plan.

What are the possible benefits and risks of participating?
If the participants do not usually use a self-management plan their asthma control may improve during the study. There is a chance that they may develop oral thrush or a hoarse voice if their self-management plan recommends extra inhaled steroid. The risk of this can be reduced by rinsing their mouth after using their steroid inhaler and it usually resolves spontaneously once the dose is reduced again. If not it is easily treated with antifungal throat lozenges or liquid prescribed by their doctor

Where is the study run from?
Nottingham Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
May 2013 to August 2017

Who is funding the study?
NIHR Health Technology Assessment Programme (UK)

Who is the main contact?
Rebecca Haydock
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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
14257; HTA 10/143/01

Study information

Scientific Title
The clinical and cost effectiveness of temporarily quadrupling the dose of inhaled steroid to prevent asthma exacerbations: a pragmatic, randomised, normal care-controlled clinical trial

Acronym
FAST

Study objectives
Determine whether the proposed asthma self-management plan reduces asthma exacerbations requiring oral steroids or unscheduled healthcare consultation for asthma.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/1014301

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Greater Manchester South, 24/04/2013, ref: 13/NW/0184

Study design
Multi-centre pragmatic randomised normal care-controlled 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
Respiratory (asthma)

Interventions
Participants will be randomised to either an asthma self-management plan which includes an increase in inhaled corticosteroid or the same plan without an increase in inhaled corticosteroid.

Intervention Type
Drug

Phase
Not Applicable

Primary outcome measure
Time to first asthma exacerbation, defined as: the need for systemic corticosteroids and/or unscheduled health care consultation for asthma.

Secondary outcome measures
1. Number of participants who exacerbate, defined as: the need for systemic corticosteroids and /or unscheduled health care consultation for asthma (i.e. reaching zone 3 or 4 of the Asthma UK self-management plan).
2. Total number of exacerbations, defined as: the need for systemic corticosteroids and/or unscheduled health care consultation for asthma (i.e. reaching zone 3 or 4 of the Asthma UK self-management plan).
3. The number of participants using systemic corticosteroids for an acute exacerbation of asthma.
4. The number of participants requiring unscheduled healthcare consultation for asthma.
5. The total number of courses of systemic corticosteroids for an acute exacerbation of asthma.
6. The total number of unscheduled healthcare consultations for asthma.
7. The time to participants requiring systemic corticosteroids for an acute exacerbation of asthma.
8. The time to unscheduled healthcare consultation for asthma
9. The area under the morning peak flow curve over 2 weeks from the point of activating stage 2 of the asthma plan.
10. Change in Asthma Control Questionnaire 2 weeks after activating stage 2 of the self-management plan.
11. Cumulative dose of inhaled and systemic steroids used in the 12 months after randomisation.
12. Cost and resource audits of both trial arms will be reported as incremental cost per asthma exacerbation prevented and cost per quality adjusted life year gained (QALY).

Overall study start date
01/05/2013

Completion date

31/08/2017

Eligibility

Key inclusion criteria
1. Male or female aged 16 years and over
2. Clinician diagnosed asthma treated with a licensed dose of inhaled corticosteroid (i.e. step 2 to 4 of the British Thoracic Society [BTS] /Scottish Intercollegiate Guidelines Network [SIGN] guidelines)
3. One or more exacerbation in the last 12 months requiring treatment with systemic corticosteroids

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
1774

Key exclusion criteria
Potential participants will be excluded on the basis of:
1. History more in keeping with smoking related chronic obstructive pulmonary disease [COPD] (smoked > 20 pack years, without evidence of significant reversibility and eosinophilia)
2. On maintenance oral steroids (i.e. step 5 BTS/SIGN guidelines)
3. Using a combination inhaler for both maintenance and relief treatment
4. Experienced an exacerbation within 4 weeks of randomisation
5. Pregnant women, lactating women or women who are planning to become pregnant

Date of first enrolment
01/05/2013

Date of final enrolment
31/01/2016

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Nottingham University Hospitals
Nottingham
United Kingdom
NG7 2UH

Study participating centre
King's Mill Hospital
Sutton-in-Ashfield
United Kingdom
NG17 4JL

Study participating centre
Glenfield Hospital
Leicester
United Kingdom
LE3 9QP

Study participating centre
Aintree University Hospital
Liverpool
United Kingdom
L9 7AL

Study participating centre
Royal Liverpool and Broadgreen hospital
Liverpool
United Kingdom
L7 8XP

Study participating centre
Freeman Hospital
Newcastle
United Kingdom
NE7 7DN

Study participating centre

Aberdeen Royal Infirmary
Aberdeen
United Kingdom
AB25 2ZN

Study participating centre
Arrowe Park Hospital
Liverpool
United Kingdom
CH49 5PE

Study participating centre
Blackpool Victoria Hospital
Blackpool
United Kingdom
FY3 8NR

Study participating centre
University Hospital of South Manchester
Manchester
United Kingdom
M23 9LT

Study participating centre
GP practices in the following CRNs:
East Midlands,
Wessex,
Eastern,
North West Coast,
North East & Cumbria,
Greater Manchester,
West Midlands (South),
West of England,
Kent, Surrey & Sussex
United Kingdom
-

Sponsor information

Organisation

University of Nottingham (UK)

Sponsor details
c/o Angela Shone
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NG7 2NR

Sponsor type
University/education

Website
http://www.nottingham.ac.uk/

ROR
https://ror.org/01ee9ar58

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
Planned publication in a high-impact peer reviewed journal by end of 2017.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/10/2016		Yes	No
Results article	results	08/03/2018		Yes	No
Results article	results	01/12/2018		Yes	No
HRA research summary			28/06/2023	No	No