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Asthma diagnosis in primary care: an evaluation of current practice

Submission date
15/09/2014

Recruitment status
No longer recruiting

Registration date
27/11/2014

Overall study status
Completed

Last Edited
15/05/2018

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Asthma is a chronic condition caused by inflammation of the small tubes (bronchi) that take air in and out of the lungs. Symptoms include coughing, wheezing, difficulties in breathing and a tightness in the chest. It can be well controlled with medication but an asthma attack – a situation whereby the symptoms suddenly become worse- can be severe enough to require treatment in hospital and can occasionally be fatal. It is a complex disease and can be difficult to diagnose on the basis of symptoms alone. Most asthma diagnoses are made by GPs in the doctors surgery (primary care) where additional tests, which may help to diagnose the disease, are often not available. Research has shown that a significant number of people are misdiagnosed as having asthma by their GP. This suggests that there needs to be some investigation into the accuracy of asthma diagnosis in primary care. Here, we want do exactly that, and look at whether providing a diagnostic referral service, which provides additional breathing tests to patients suspected of having asthma, would increase this accuracy. We also want to find out if a central diagnostic service would be acceptable to patients and healthcare practitioners.

Who can participate?
Adults aged over 18 who have recently been diagnosed with asthma in a primary care setting.

What does the study involve?
Participants are asked to visit a study site on one occasion. During this visit they complete a number of breathing tests, an allergy test and a questionnaire, all of which are currently recommended to help diagnose asthma. We then look at their results to see whether or not the participant does actually have asthma. There is then a 6 month follow up period whereby data on each participants prescriptions and any hospital admissions are collected electronically. Participants and healthcare professionals are also asked questions about the current asthma diagnosis service provided and whether they think a central referral service for asthma diagnosis could work.

What are the possible benefits and risks of participating?
With consent, results of the tests completed during the study visit will be given to participants GPs which may help them to manage and treat the individual and confirm diagnosis. The risks of

taking part in the study are very small, one of the breathing tests can make people feel tight chested for a short period of time. This is, however, dealt with quickly using a salbutamol inhaler.

Where is the study running?
The study will run across the NHS Fife area (Scotland)

When is the study starting and how long is it expected to run for?
April 2015 to March 2016

Who is funding this study?
Chief Scientist Office Scotland (UK) - to be confirmed.

Who is the main contact?
Prof. C Jackson
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
JAK002

Study information

Scientific Title
Asthma Diagnosis in primary care: an Evaluation of current PracTice and pilot evaluation of the feasibility of a central diagnostic service

Acronym
ADEPT

Study objectives
Is a centralised referral service for asthma diagnosis feasible and will it improve diagnostic accuracy?

1. Primary Objective: Investigate the feasibility and acceptability of a centralised service for asthma diagnosis in the community
2. Secondary Objectives: Assess the current accuracy of asthma diagnosis in primary care

Evaluate the current process of asthma diagnosis using qualitative data.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Pilot study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
GP practice

Study type(s)
Diagnostic

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 diagnosis in primary care

Interventions
Diagnostic tests including:
1. Spirometry
2. FENO
3. Mannitol challenge
4. Skin prick test
5. Asthma quality of life questionairre.

Intervention Type

Other

Primary outcome measure
1. Uptake of referral service at GP and patient level
2. Thematic evaluation of semi-structured interviews relating to referral service
All outcomes will be measured at end of study recruitment.

Secondary outcome measures
1. Proportion of correct asthma diagnoses made in primary care confirmed by diagnostic review
2. Thematic evaluation of semi-structured interviews relating to current service
All outcomes will be measured at end of study recruitment.

Overall study start date
01/04/2015

Completion date
31/03/2016

Eligibility

Key inclusion criteria
1. Registered at GP practice within NHS Fife
2. Recent diagnosis of asthma received in primary care
3. BTS Step 1 (Prescribed reliever medication only)
4. Age 18 years old or over
5. Ability to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Lower respiratory tract infection and/or oral corticosteroids in last 6 weeks
2. Women who are known to be pregnant or breastfeeding
3. Known hypersensitivity to mannitol
4. Any significant medical condition which may impair ability to complete diagnostic tests for example aortic, thoracic or cerebral aneurysm, recent eye surgery, uncontrolled hypertension, MI or CVA in past 6 months

Date of first enrolment
01/04/2015

Date of final enrolment
31/03/2016

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of St Andrews
St Andrews
United Kingdom
KY16 9TF

Sponsor information

Organisation
University of St Andrews (UK)

Sponsor details
Reasearch BD and Contracts
The Gateway
North Haugh
St Andrews
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Sponsor type
University/education

Website
http://www.st-andrews.ac.uk

ROR
https://ror.org/02wn5qz54

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office Scotland (UK) - to be confirmed

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