ISRCTN36918958 https://doi.org/10.1186/ISRCTN36918958

A cluster randomised controlled trial to assess the effectiveness and costs of implementing asthma risk registers to identify and improve management of high risk asthma patients in primary care

Submission date 04/05/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/05/2007	**Overall study status** Completed	
Last Edited 19/11/2012	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
06/047

Study information

Scientific Title

Acronym
ARRISA (At-Risk Registers In Severe Asthma study)

Study objectives
Compared to routine care, the implementation and use of primary care-based registers of patients at high risk from severe and life-threatening exacerbations of asthma will:
1. Reduce exacerbations in these patients
2. Result in overall reduced healthcare costs associated with managing these patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Norfolk Research Ethics Committee on the 11th December 2006. Current protocol with minor amendments approved on 3rd March 2007 (ref: 06/Q0101/200).

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Asthma

Interventions
Practices randomised to the intervention arm will add at-risk asthma patients to an at-risk register. Identified patients will be added to an asthma risk register involving:
1. Electronic tagging of each patients record on the practice computer system with a

customisable alert (e.g. high risk asthma patient, prioritise appointment) that needs actively clearing from the screen whenever the record is called up, and
2. Placing a similar marker in patients written records

This designation will be made available to all practice staff and, where possible, out-of-hours services. In addition, all staff will be given a one hour training session, delivered by a General Practitioner (GP) (Dr Mike Noble) and asthma nurse (Ms Jenny Windley) experienced in implementing and using an asthma risk register at their practice, on the relevance of the alerts and action to be taken when a high risk patient contacts the practice.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Moderate-severe asthma exacerbations, measured at one year.

Secondary outcome measures
1. Exacerbations from:
1.1. Death or hospitalisation
1.2. Emergency attendance (at the hospital, the practice or via a home visit)
1.3. Out-of-hours medical contact
1.4. A course of oral prednisolone or a boost in oral steroids for those receiving them regularly
2. Asthma-related routine primary and secondary care attendances and medication use
3. Healthcare costs

All secondary outcomes measured at one year.

Overall study start date
01/03/2007

Completion date
28/02/2010

Eligibility

Key inclusion criteria
PRACTICES:
1. Participation is open to all practices with adequate computer systems which are used to support routine consultations
2. Practices covering urban and rural populations, deprived and affluent areas and various practice sizes and set-ups

PATIENTS:
High risk patients aged 5+ years at participating practices will, according to British asthma guideline recommendations, be identified on the basis of having:
1. Severe asthma, recognised by one or more of:
1.1. Previous near-fatal asthma
1.2. Hospital admission for asthma in the last five years

1.3. Two or more attendances at Accident and Emergency (A&E) or out-of-hours services for asthma in the last year
1.4. Requiring step four or five treatment
1.5. Brittle asthma

PLUS:

2. A record in the notes (of patients or their primary carers for children) of adverse behavioural or psychosocial characteristics including one or more of:
2.1. Poor adherence to recommended management
2.2. Failure to attend primary care or hospital appointments
2.3. Self-discharge from hospital
2.4. Psychosis, depression, other psychiatric illness or deliberate self-harm
2.5. Current or recent major tranquiliser use
2.6. Alcohol or drug abuse
2.7. Denial
2.8. Obesity
2.9. Learning difficulties
2.10. Employment problems
2.11. Income problems
2.12. Social isolation
2.13. Childhood abuse
2.14. Severe domestic, marital or legal stress

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
24 - 36 practices (416 - 524 patients)

Key exclusion criteria
PRACTICES:
Those with pre-existing at-risk asthma registers or similar strategies to study intervention.

PATIENTS:
Patients who meet the inclusion criteria but are felt not appropriate to be included on an at-risk register for some other factor will be individually negotiated.

Date of first enrolment
01/03/2007

Date of final enrolment
28/02/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Medicine
Norwich
United Kingdom
NR4 7TJ

Sponsor information

Organisation
Asthma UK (UK)

Sponsor details
Summit House
70 Wilson Street
London
United Kingdom
EC2A 2DB
+44 (0)20 7786 4940
CWright@asthma.org.uk

Sponsor type
Charity

Website
http://www.asthma.org.uk

ROR
https://ror.org/03z7xev21

Funder(s)

Funder type
Charity

Funder Name
Asthma UK (UK) (ref: 06/047)

Alternative Name(s)
Asthma UK, Asthma + Lung UK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

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	01/12/2012		Yes	No