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CRP study: The value of C-reactive protein (CRP) testing in acutely ill children

Submission date
22/07/2013

Recruitment status
No longer recruiting

Registration date
22/07/2013

Overall study status
Completed

Last Edited
14/01/2016

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Acute illness in children is one of the most common problems in general practice. In the UK, acute infections result in four consultations per person each year in children aged less than 1 year, and an average of 1.3 consultations per person each year in children aged 1-15 year. Febrile illness (seizures due to high body temperature) accounts for 20% of all visits to the paediatric emergency department.
Clinical features have moderate ability to identify a subgroup of children with an increased risk of serious infections The National Institute for Health and Care Excellence (NICE) recommends the measurement of vital signs including temperature, breathing rate and pulse in each child But studies show that primary care doctors measure temperature in less than half of children, with even lower rates for breathing rate and pulse. The use of age-adjusted percentiles may increase interpretability and therefore uptake of measuring vital signs In addition, combining the results for all vital signs has recently been shown to be able to rule out serious infections. However, the evidence also clearly shows that vital signs and other clinical features result in a fairly large number of false positives, i.e. too many children will be considered potentially at risk for a serious infection Therefore, to avoid inappropriate referral to secondary care but improve recognition at the same time, additional testing is necessary. The blood level of C-reactive protein (CRP) has moderate to good ability to rule in or rule out serious infections in children attending emergency departments or out-of-hours services (CRP is produced by the liver. If there is more CRP than usual, there is inflammation in your body). At present, point-of-care CRP tests are available that could be used in general practice. The Afinion Analyzer produces a result within minutes and requires only a finger prick with limited handling of the sample afterwards. Introducing point-of-care CRP testing in the routine management of acutely ill children may also affect doctors prescribing of antibiotics. A large trial could assess whether CRP point-of-care testing is able to assist in the early recognition of serious infections and in the improved targeting of antibiotic prescribing in children with an acute illness. However, several factors necessary for the adequate planning of such a study are unknown at present, making an initial small study necessary. The main objective is to assess how many children and parents/guardians would agree to be recruited to a trial involving a minimally invasive blood test. The other objectives are to estimate effect size - to confirm that the effect achieved by measuring blood CRP is consistent with a clinically important change in antibiotic prescription rates, referral rates, hospital admission rates, and additional testing rates In addition, we want to evaluate whether

the blood test is acceptable to children and parents/guardians, feasible for a nurse, and increases diagnostic certainty for GPs.

Who can participate?
Male or female, aged 1 month to 16 years presenting to out-of-hours with an acute illness of a maximum of 5 days.

What does the study involve?
The study nurse will measure the vital signs of all children in the study. Measurement of temperature, breathing rate and heart rate is part of the normal routine care of acutely ill children. Participants will be randomly allocated to one of two groups. One group will undergo CRP testing while the other group will receive standard care. The CRP test will be done by the study nurse as a near patient procedure (this requires a drop of blood normally obtained by finger prick). This information will then be given to the doctor to assist their diagnosis.

What are the possible benefits and risks of participating?
The study will possibly lead to an improvement in the diagnosis from the doctor. There is no risk of harm from measuring vital signs; this is recommended by NICE guidelines in every child presenting with an acute illness. The finger prick required for the CRP test will be perceived as painful by some children, although the pain is minimal and will go away quickly.

Where is the study run from?
The Oxford Health NHS Foundation Trust Out of Hours Clinic

When is the study starting and how long is it expected to run for?
July 2013 to December 2013

Who is funding the study?
NIHR School of Primary Care Research and the University of Oxford

Who is the main contact?
Mr David Timmins
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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
14824

Study information

Scientific Title
A pilot study on the effects of adding C-reactive protein point-of-care testing in the management of acutely ill children in primary care

Acronym
CRP

Study objectives
This is a pilot study aiming to address the following outcomes:
1. To estimate recruitment rates for a future larger trial on the efficacy of CRP testing in acutely ill children.
To assess acceptability and feasibility of performing a point-of-care blood test in children, and estimate tentative effects on differences in clinical decision making.
2. To analyse the usefulness of presenting vital signs measurements in clinically useful formats.
Recruitment for this study is opportunistic, potentially eligible patients will be invited to join the study when they present at the Out of Hours Surgery. Patients that consent and are eligible will be randomised between the intervention arm and standard care.

More details can be found at: http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=14824

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC approval date 21/03/2013, ref: 13/SC/0045

Study design
Cohort study with nested randomised controlled trial; Design type: Screening

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
Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions
Patients that consent and are eligible will be randomised between the intervention arm and standard care.

CRP Test, Patients will receive a finger prick in order to obtain a blood sample for a C-Reactive Protein Test

Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Recruitment Rate; Timepoints: Recruitment rate of children to the study over the length of the trial, approximately 6 months.

Secondary outcome measures
1. Difference in antibiotic prescription rates.
2. Difference in referrals.
3. Difference in additional testing rates.
4. Difference in hospital admission.
5. Acceptability of the blood test by children and their parents/guardians.
6. Feasibility of the blood test by a nurse.
7. Impact of the blood test on the GPs diagnostic certainty.
8. Impact of the vital signs measurements applied on percentiles and prediction score on GPs diagnostic certainty.

Overall study start date
08/07/2013

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Participant/parent or guardian is willing and able to give informed consent for participation in the study.
2. Male or Female, aged 1 month to 16 years.

3. Presenting to out-of-hours with an acute illness of a maximum of 5 days.
4. A subset of children, i.e. Those with a body temperature >=38°C, will be randomised to CRP or no CRP testing.

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Months

Upper age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 700; UK Sample Size: 700

Key exclusion criteria
1. Acute trauma
2. Clinically unstable warranting immediate care
3. Prior inclusion in the study
4. Prior inclusion in another clinical trial of an investigational medicinal product in the last 90 days or any other research in the last 30 days

Date of first enrolment
08/07/2013

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Primary Health Care
Oxford
United Kingdom
OX1 2ET

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Department of Clinical Pharmacology
Radcliffe Infirmary
Woodstock Road
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OX2 6HE

Sponsor type
University/education

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

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
University of Oxford

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	01/04/2016		Yes	No
HRA research summary			28/06/2023	No	No