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Measuring temperature in children

Submission date
26/06/2017

Recruitment status
No longer recruiting

Registration date
27/07/2017

Overall study status
Completed

Last Edited
06/08/2024

Condition category
Other

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

Plain English summary of protocol

Background and study aims
National guidelines recommend measuring temperature whenever a child is ill using a digital thermometer in the armpit or an ear thermometer. However, armpit thermometers require healthcare professionals to undress the child and hold the thermometer under the arm for at least 30 seconds. Ear thermometers are easier to use, but may be inaccurate due to ear wax or insufficient straightening of the ear canal. A non-contact thermometer is a no touch thermometer, designed to allow to take children's temperature on the forehead without touching the child and potentially causes less distress to children. This thermometer works by measuring infrared emissions from the body, which only takes a few seconds. The aim of the study is to assess the agreement between two NCIT versus ear and armpit thermometers in children aged 5 years or under.

Who can participate?
Unwell children aged 0-5 years (maximum illness 14 days) presenting to GP practice or out-of-hours service.

What does the study involve?
Participating children have their background details (age, gender, etc) recorded. They then have their body temperature measured using an armpit thermometer, an ear thermometer and twice with two different non-contact infrared thermometers. Parents/guardians and children are asked to rate each thermometer by preference.

What are the possible benefits and risks of participating?
There are no direct benefits of participating. There are no notable risks, however, it does take up a small amount of participant's time and could be distressing to an unwell child.

Where is the study run from?
The study is run from the University of Oxford and takes place in GP practices and out-of-hours service in Oxfordshire (UK).

When is the study starting and how long is it expected to run for?
December 2016 to August 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
1. Gail Hayward
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2. George Edwards
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
33590

Study information

Scientific Title
MEasuring TemperatuRe In Children: Non-contact infrared thermometers for measuring body temperature in acutely ill children: a method comparison study

Acronym
METRIC

Study objectives
The aim of the study is to assess the agreement between two Non-Contact Infrared Thermometers (Thermofocus and Firhealth) versus electronic axillary and infrared tympanic thermometers in children who present with an acute illness in primary care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central-Berkshire Research Ethics Committee, 17/03/2017, 17/SC/0068

Study design
Non-randomised; Observational; Design type: Cross-sectional

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Primary Care, Primary sub-specialty: Children; UKCRC code/ Disease: Other/ General symptoms and signs

Interventions
Parents/guardians of children aged five years or under are approached by the research assistant while they are in the GP waiting area for possible recruitment. The research assistant records demographic information (including household composition, parental age and ethnicity) and baseline information (including prior fever medication use, parental impression of fever, fever duration) for each eligible child (after verbal consent from parents/guardians). Subsequently, the research assistant measures body temperature with four different thermometers, in a random order predetermined by the use of a random number generator. Children under four weeks of age do not have the tympanic thermometer measurement. Temperature measurements are performed consecutively in the shortest time frame possible, and no medication or drinks are administered between measurements. Once the four primary measurements are complete, a second measurement is taken with each Non-Contact Infrared Thermometer (NCIT) to evaluate reproducibility. Failures to perform measurements due to lack of cooperation of the child after three attempts, mechanical issues (operational or technological failure) and clinically implausible readings (based on clinician’s assessment) are recorded.

Parents are asked to score the acceptability of each thermometer on a visual analogue scale and rank the thermometers by preference. Children`s reaction to the different measurements are

recorded by the Patient Discomfort Scale. Children aged four to five years are asked to score each thermometer using the Wong-Baker Face pain rating scale. Parents and children are blinded to the temperature measurements until they have rated their acceptability to avoid bias.

Verbal consent is sought for further contact regarding a qualitative telephone interview study to explore parent's views and preferences regarding the different thermometers used. A subset of parents who consent to further contact are approached for an interview based on a purposive sampling procedure.

Verbal informed consent is also obtained from parents to keep their contact email or telephone number securely. This would be in order that future contact could be made to obtain written informed consent to access details of their child's medical notes regarding re-attendance, secondary care referrals and admissions in the 30 days after the initial contact.

There is only one study visit, which is at the GP practice or out-of-hours service where the children are recruited and all interventions are performed.

Intervention Type
Other

Primary outcome(s)
Agreement between the Thermofocus NCIT and electronic axillary thermometer is assessed using the limits of agreement at study visit

Key secondary outcome(s))
1. Agreement between the Thermofoucs NCIT and Infrared tympanic thermometer (and therefore between tympanic and axillary) is assessed using the limits of agreement at study visit
2. Agreement between the Thermofocus NCIT and Firhealth NCIT is assessed using the limits of agreement at study visit
3. The ability of NCITs to detect fever (≥38°C) is assessed using accuracy of diagnosing fever at study visit
4. The failure rates of all thermometers is assessed using proportion of failed measurements at study visit
5. The acceptability of the four thermometry methods is assessed using acceptability to parents and children if applicable at study visit
6. The reproducibility of measurements made with the two NCITs is assessed using intra-observer variability at study visit

Tertiary outcome:
Association between temperature readings and medication use at the index consultation with incidence of repeat consultations in in-hours and out-of-hours general practice, secondary referrals and hospital admission in the 30 days following initial recruitment is assessed by reviewing children's medical notes.

Completion date
31/08/2018

Eligibility

Key inclusion criteria

1. Parent or guardian is willing and able to give informed consent for participation in the study.
2. Male or Female, aged 0 to 5 years
3. Presenting to a GP practice or out-of-hours service with an acute illness of a maximum of 14 days duration

Inclusion criteria for qualitative interviews:
1. Recruited to main study
2. Able to conduct a telephone interview in English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
0 years

Upper age limit
5 years

Sex
All

Total final enrolment
401

Key exclusion criteria
1. Acute trauma
2. Clinically unstable warranting immediate care
3. Prior inclusion in the study
4. Unable to understand trial material in English

Date of first enrolment
19/04/2017

Date of final enrolment
31/08/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nuffield Department of Primary Care Health Sciences
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Sponsor information

Organisation
University of Oxford

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

Results and Publications

Individual participant data (IPD) sharing plan

Once all publications are complete the datasets generated during and/or analysed during the current study will be available upon request from Gail Hayward (Gail.hayward@phc.ox.ac.uk) and George Edwards (george.edwards@phc.ox.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/03/2020	31/03/2020	Yes	No
Results article		01/10/2020	06/08/2024	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version 2	10/03/2017	10/08/2022	No	No