ISRCTN34931655 https://doi.org/10.1186/ISRCTN34931655

Antibiotic prescribing habits in children with infections in primary care in Latvia and the effect of a multifactorial intervention (family physician education and C reactive protein point-of-care testing) on a change of habits

Submission date
11/05/2024

Recruitment status
No longer recruiting

Registration date
15/07/2024

Overall study status
Completed

Last Edited
30/10/2025

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 infection in children is one of the most common reasons for attending family physicians (FPs) and these visits often result in antibiotic prescriptions. As self-limiting viral infections are predominant, at least 30% of antibiotics prescribed in outpatient settings are considered to be unnecessary. The aim of this study is to evaluate the effect of the combination of two interventions – access to C reactive protein (CRP) point-of-care testing in FPs' practices and educational training for FPs – on the antibiotic prescribing rate for acutely ill children.

Who can participate?
Child-age patients (1 month up to 17 years) with acute infections visiting FPs in face-to-face consultations

What does the study involve?
80 FPs were divided into two groups of 40 FPs: Group 1 and Group 2. In the first period, the FPs in Group 1 received two interventions (CRP POCT and a live educational session) and Group 2 continued usual care as a control without any interventions. In the second study period, FPs were switched - Group 2 received both interventions (CRP testing and a live educational session) and Group 1 continued usual care without CRP testing anymore.
The 4-hour live educational session included principles of antibiotic resistance and safer prescribing of antibiotics, as well as new recommendations for the management of respiratory infections and fever in children introduced in 2019 in Latvia. FPs also received educational material in video and printed format after the session.
FPs were given a system for measuring CRP in blood obtained via a finger prick. Each FP was individually tutored by the diagnostic test company on how to perform the CRP test during a

face-to-face meeting, and ongoing support by the company was available to the FP during the intervention period. FPs ordered a CRP test only if they believed the result would help them make a more informed decision on antibiotic necessity after a clinical assessment.

What are the possible benefits and risks of participating?
There were no risks for patients because FPs ordered a CRP test only if they believed the result would help them make a more informed decision on antibiotic necessity after a clinical assessment not for all patients. As CRP point-of-care testing is not incorporated into Latvian primary care, it provided the opportunity to get new experience with CRP testing in daily practice. Also, FPs were introduced to the new clinical pathways and guidelines.

Where is the study run from?
Riga Stradins University (Latvia)

When is the study starting and how long is it expected to run for?
February 2019 to May 2021

Who is funding the study?
Riga Stradins University (Latvia)

Who is the main contact?
Zane Likopa, zane.likopa@bkus.lv

Contact information

Type(s)
Public, Scientific

Contact name
Mrs Zane Likopa

ORCID ID
https://orcid.org/0000-0002-7048-9783

Contact details
Kaktusu 3
Riga
Latvia
LV 1024
+371 (0)29482308
zane.likopa@bkus.lv

Type(s)
Principal investigator

Contact name
Prof Jana Pavare

ORCID ID
https://orcid.org/0000-0001-8469-4713

Contact details
Vienibas gatve 45
Riga
Latvia
LV-1004
+371 (0)29482308
jana.pavare@rsu.lv

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
6-3/5/21

Study information

Scientific Title
Effect of combination of point-of-care C-reactive protein testing and family physician education on reducing antibiotic prescribing for children presenting with acute infections in primary care in Latvia: a randomised controlled intervention study

Study objectives
A combined intervention – family physician education and C reactive protein point-of-care testing – will reduce the frequency of prescription for antibiotics in children with infections in primary care.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 30/05/2019, Research Ethics Committee of Riga Stradins University (Dzirciema street 16, Riga, LV - 1007, Latvia; +371 (0)29482308; pek@rsu.lv), ref: 6-3/5/21

Study design
Randomized controlled intervention study

Primary study design
Interventional

Study type(s)
Diagnostic, Treatment

Health condition(s) or problem(s) studied
Reducing antibiotic prescribing for children with acute infections

Interventions
This was a randomized controlled intervention study, with randomization at the family physician (FP) practice level. The FPs were stratified according to practice location, and each stratum was divided into two groups of 40 FPs using random numbers generated by MS Excel Random Number function. The effect of the combination of two interventions, a live educational session and C reactive protein point-of-care testing (CRP POCT), was evaluated.

80 FPs were divided into two groups of 40 FPs – Group 1 and Group 2. In the first period, the FPs in Group 1 received two interventions (CRP POCT and a live educational session) and Group 2 continued usual care as a control without any interventions. In the second study period FPs were switched - Group 2 received both interventions (CRP POCT and a live educational session) and Group 1 continued usual care without CRP POCT anymore.

The 4-hour live educational session included principles of antibiotic resistance and safer prescribing of antibiotics, as well as new recommendations for the management of respiratory infections and fever in children introduced in 2019 in Latvia. FPs also received educational material in video and printed format after the session.

FPs were given the Orion Diagnostica QuikRead go CRP POCT system for the quantitative determination of CRP in blood with a sample volume of 20 µl obtained via a finger prick. This system has a measuring range of 5–200 mg/L and the result is available within 2 minutes. As CRP cut-off levels for children in primary care are currently undetermined, the FPs did not receive any guidelines on the interpretation of results. Each FP was individually tutored by the diagnostic test company on how to perform the CRP test during a face-to-face meeting, and ongoing support by the company was available to the FP during the intervention period. FPs ordered a CRP test only if they believed the result would help them make a more informed decision on antibiotic necessity after a clinical assessment.

Intervention Type
Mixed

Primary outcome(s)
Antibiotic prescribing at the index consultation for patients with acute illnesses with symptoms less than 5 days visiting FP in face-to-face consultations, measured using dichotomous variables - prescribed, not
prescribed

Key secondary outcome(s))
CRP testing frequency measured using continuous variable - number of tests performed and CRP level measured with Orion Diagnostica QuikRead go CRP POCT system during index consultation using four categories (<20 mg/L; 20.1 mg/L - 50.0 mg/L; 50.1 mg/L - 99.0 mg/L, >100 mg/L)

Completion date
01/05/2021

Eligibility

Key inclusion criteria
1. Current clinical signs of acute infection for less than 5 days
2. Aged 1 month up to 17 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
1 months

Upper age limit
17 years

Sex
All

Total final enrolment
3801

Key exclusion criteria
1. Age under 1 month
2. Re-convalescent stage of infectious disease
3. Use of antimicrobial therapy before the time of the visit

Date of first enrolment
15/11/2019

Date of final enrolment
30/04/2021

Locations

Countries of recruitment
Latvia

Study participating centre
80urban and rural family physician practices in Latvia
Latvia
-

Sponsor information

Organisation
Riga Stradiņš University

ROR
https://ror.org/03nadks56

Funder(s)

Funder type
University/education

Funder Name
Rīgas Stradiņa Universitāte

Alternative Name(s)
Rīga Stradiņš University, Rīga Stradiņš University, Universitas Rigensis Stradina, Riga Medical Institute, Medical Academy of Latvia, RSU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Latvia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from Zane Likopa (zane.likopa@gmail.com). The data that support the findings of this study (anonymized dataset) are available on request from the corresponding author.
According to the decision of the Research Ethics Committee of Riga Stradins University patient consent was not required because only the participating FP were exposed to the study interventions, but patients did not undergo any intervention and CRP testing was used only according to clinical indications as in routine practice. Patients were informed about the objective of the project, and they were told that specific anonymous clinical information related to the consultation was collected for the study purposes.
All data is anonymous and there is no information that can be used to identify individual registry patients by personal analysis of the data. Participating FP is also considered to be confidential information.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/10/2025	30/10/2025	Yes	No
Interim results article		17/08/2021	16/05/2024	Yes	No
Interim results article		21/09/2022	16/05/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes