

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/07/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/07/2024	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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?

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Contact information

Type(s)

Public, Scientific

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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 (Dzirnciema 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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Diagnostic, Treatment

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

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)

Overall study start date

01/02/2019

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

Age group

Child

Lower age limit

1 Months

Upper age limit

17 Years

Sex

Both

Target number of participants

2284 (571 in each group)

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

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Sponsor type

University/education

Website

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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

Publication and dissemination plan

The study results are going to be published in four following publications:

1. Antibiotic prescribing habits – published 2021

Likopa, Z., Kivite-Urtane, A. and Pavare, J. 2021. Latvian Primary Care Management of Children with Acute Infections: Antibiotic-Prescribing Habits and Diagnostic Process Prior to Treatment. *Medicina (B. Aires).*, 57. doi: 10.3390/MEDICINA57080831.

2. The first study period results - published 2021

Likopa, Z., Kivite-Urtane, A., Silina, V. and Pavare, J. 2021. Impact of educational training and C-reactive protein point-of-care testing on antibiotic prescribing in rural and urban family physician practices in Latvia: a randomised controlled intervention study. doi: 10.1186/s12887-022-03608-4.

3. Overall results of the study - planned to be published in May 2024

Likopa, Z., Kivite-Urtane, A. and Pavare. Effect of combination of point-of-care C-reactive protein testing and family physician education and long-term effect of education on reducing antibiotic prescribing for children presenting with acute infections in primary care in Latvia: A randomised controlled intervention study

4. Changes in antibiotic prescribing habits (diagnostic process, antibiotic prescribing and choice of antibiotics) after interventions - planned to published in August 2024

Likopa, Z., Kivite-Urtane, A. and Pavare. Changes in antibiotic prescribing habits (diagnostic process, antibiotic prescribing and choice of antibiotics) after introduction of point-of-care C-reactive protein testing and family physician education in primary care in Latvia: A randomised controlled intervention study

Intention to publish date

01/08/2024

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?
Interim results article		17/08/2021	16/05/2024	Yes	No
Interim results article		21/09/2022	16/05/2024	Yes	No