ISRCTN55473884 https://doi.org/10.1186/ISRCTN55473884

A randomized clinical trial to test the effectiveness of a multifaceted intervention to increase HPV vaccination rates

Submission date
01/06/2021

Recruitment status
No longer recruiting

Registration date
04/06/2021

Overall study status
Completed

Last Edited
14/07/2025

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Human papillomavirus (HPV) is a viral infection passed between people through skin-to-skin contact. Some types can cause genital warts or cancer. The HPV vaccination coverage rate in Switzerland is below the target rate of 80% that has been set as a goal by the Ministry of Health. The aim of this study is to find out whether a multifaceted, targeted intervention on general practitioners (GPs) increases HPV vaccination in Swiss Primary Care.

Who can participate?
Physicians who work in primary care and patients for whom vaccination is recommended according to the currently valid vaccination schedule can participate in the study.

What does the study involve?
The study includes about 4 hours of training on HPV and HPV vaccination for the intervention group. Physicians in the control group receive general training on the topic of vaccination, without a special focus on HPV. The overall number of HPV vaccinations is reported at 6 months.

What are the possible benefits and risks of participating?
If the intervention leads to an increase in vaccination rates, it may increase the national vaccination rate against HPV. As there are no interventions at the patient level, and vaccinations only are given if recommended according to the national vaccination schedule, there are no study-specific risks for participating patients.

Where is the study run from?
Institute for Primary Care, University Hospital Zurich/University of Zurich (Switzerland)

When is the study starting and how long is it expected to run for?
January 2020 to December 2023

Who is funding the study?
1. MSD Merck Sharp & Dohme AG, a subsidiary of Merck & Co., Inc
2. Institute for Primary Care, University Hospital Zurich/University of Zurich (Switzerland)

Who is the main contact?
Dr. med. Andreas Plate
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1.2

Study information

Scientific Title
Impact of a multifaceted, targeted intervention on the human papillomavirus vaccination rate in Swiss Primary Care: a cluster randomized controlled trial

Acronym
HPV RCT

Study objectives

The researchers predict that a multifaceted, targeted intervention with a focus on teaching a presumptive announcement recommendation style will result in an increase in the HPV vaccination (HPVv) numbers in Swiss Primary Care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/12/2020, Local Ethics Committee, Zurich (Kantonale Ethikkommission, Stampfenbachstrasse 121, 8090 Zürich, Switzerland; +41 (0)43 259 79 70; admin.kek@kek.zh.ch), ref: 2020 - 02341

Study design
Prospective cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Prevention

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
Human papillomavirus

Interventions
Study physicians will be randomized into two groups (control and intervention). A statistician not involved in the study performs the randomization. They will use stratified randomization.
1. GPs who are not already a member of the cantonal vaccination programs are randomized after stratification
2. GP practice level. If more than one GP from the same practice participates in the study, the researchers will allocate them to the same group
3. Number of performed HPVv during the baseline period

Both groups receive a general study instruction, which consists of basic information about the order of the study, study conduct and reporting. Both groups will receive a basic educational session about vaccination.

Control group:
All GPs in the control group will receive a basic educational session about vaccination and the current national vaccination recommendations. The session will include all basic information

about HPV and HPV vaccination to ensure that all GPs know how to provide vaccinations according to the current recommendations.

Intervention group:
In addition to the basic educational session about vaccinations, GPs in the intervention group will receive an intervention consisting of three parts:
1. Detailed information about HPV and HPVv
2. Information about the announcement communication method in delivering vaccinations
3. Information about logistics and administrative issues regarding the HPVv

Duration of the intervention: about 3-4 hours of training.
Follow-up. There is no specific follow up of patients in this study

Intervention Type
Other

Primary outcome measure
Overall number of HPVv given in the first 6 months, reported in a specific case report form (CRF) at month 6

Secondary outcome measures
Current secondary outcome measures as of 13/02/2023:

1. HPVv uptake (1st dose [with exception of baseline period and month 6] and overall vaccination doses) in the intervention group and control group, reported in a specific case report form (CRF) during the baseline period and at 3, 6, and 12 months
2. The change in HPVv uptake (overall vaccination doses) reported in a specific case report form (CRF) from baseline to defined time points (3, 6 and 12 months) between the intervention group and control group
3. The change in HPV and HPVv knowledge and attitudes (at GP level) measured using a questionnaire at baseline and month 6
4. Basic demographic data of HPV vaccinated patients (gender and age), provided by GPs in the CRF after 6 and 12 months
5. HPVv first vaccination or booster vaccination, request of patient or recommendation by GP (or both), and HPVv given alone or in combination with other vaccines, provided by GPs in the CRF after 6 and 12 months

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Previous secondary outcome measures:

1. HPVv uptake (1st dose [with exception of baseline period and month 6] and overall vaccination doses) in the intervention group and control group, reported in a specific case report form (CRF) during the baseline period and at 2, 4, 6, and 12 months
2. The change in HPVv uptake (overall vaccination doses) reported in a specific case report form (CRF) from baseline to defined timepoints (2, 4, 6 and 12 months) between the intervention group and control group
3. The change in HPV and HPVv knowledge and attitudes (at GP level) measured using a questionnaire at baseline and month 6
4. Basic demographic data of HPV vaccinated patients (gender and age), provided by GPs in the CRF after 6 and 12 months

5. HPVv first vaccination or booster vaccination, request of patient or recommendation by GP (or both), and HPVv given alone or in combination with other vaccines, provided by GPs in the CRF after 6 and 12 months

Overall study start date
01/01/2020

Completion date
31/12/2023

Eligibility

Key inclusion criteria
The study patient population is equal to the target population of the vaccines of interest. GPs will provide vaccinations according to the current Swiss vaccination recommendations publicized by the Swiss Ministry of Health (Swiss vaccination schedule 2020)

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
1980

Total final enrolment
5329

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/09/2021

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
Switzerland

Study participating centre

Institute of Primary Care
Pestalozzistrasse 24
Zürich
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8091

Sponsor information

Organisation
MSD (Switzerland)

Sponsor details
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Sponsor type
Industry

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ROR
https://ror.org/009nc9s30

Funder(s)

Funder type
Industry

Funder Name
Merck Sharp and Dohme

Alternative Name(s)
MSD United Kingdom, Merck Sharp & Dohme, Merck Sharp & Dohme Corp., MSD

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
Universitätsspital Zürich

Alternative Name(s)
University Hospital Zurich, USZ

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Germany

Funder Name
Universität Zürich

Alternative Name(s)
University of Zurich, Switzerland, University of Zurich, UZH

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Switzerland

Results and Publications

Publication and dissemination plan
All results will be published in an international peer-reviewed journal. Currently no further documents are available.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to internal regulations

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan	version 1.0	12/10/2022	13/02/2023	No	No
Results article		04/07/2025	07/07/2025	Yes	No