

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

<b>Submission date</b> 01/06/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/06/2021	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/07/2025	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> 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

### Contact name

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### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

## **Study type(s)**

Prevention

## **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(s)**

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

### **Key secondary outcome(s)**

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

### **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

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**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

Switzerland

8091

## Sponsor information

**Organisation**

MSD (Switzerland)

**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

## 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?
<a href="#">Results article</a>		04/07/2025	07/07/2025	Yes	No
<a href="#">Statistical Analysis Plan</a>	version 1.0	12/10/2022	13/02/2023	No	No