

# Randomised trial of two versus three doses of human papillomavirus (HPV) vaccine in India

<b>Submission date</b> 17/03/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/06/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/10/2021	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**  
NCT00923702

**Secondary identifying numbers**  
N/A

# Study information

## Scientific Title

Randomised trial of two versus three doses of human papillomavirus (HPV) vaccine in India

## Study objectives

The primary study hypothesis is that a two-dose human papillomavirus (HPV) vaccine regimen over six months would offer similar immunogenicity and protection as that of a three-dose regimen to girls against infection and cervical neoplasia caused by HPV types included in the vaccine and any oncogenic HPV types.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

International Agency for Research on Cancer (IARC) Institutional Review Board, 18/02/2008

## Study design

Two-arm multicentre cluster randomised trial (randomisation unit = villages)

## Primary study design

Interventional

## Secondary study design

Cluster randomised trial

## Study setting(s)

Not specified

## Study type(s)

Prevention

## Participant information sheet

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

## Health condition(s) or problem(s) studied

Cervical precancerous lesions and cervical cancer

## Interventions

Vaccination with the prophylactic quadrivalent vaccine of Merck (Gardasil®) which targets HPV 16, 18, 6 and 11 types for prevention of infection with the most common HPV 16 and 18 high risk types and associated cervical intraepithelial neoplasia (CIN).

The participants will be randomly allocated in equal numbers to receive either two or three doses of the vaccine. Each injection contains 20 microgram type 6, 40 microgram type 11, 40 microgram type 16, and 20 microgram type 18. Girls in the two-dose group will receive the vaccine at Day 1 and Day 180, girls in the three-dose group will receive the vaccine at Day 1, Day 60, and Day 180.

## **Intervention Type**

Biological/Vaccine

## **Primary outcome measure**

1. The relative type specific immunogenicity in terms of the presence of serum neutralising antibodies to HPV 16 and 18 (serum anti-HPV L1 antibody [sL1Ab]) measured using a competitive Luminex immunoassay in blood sample collected from a 15% sample of girls at 7, 12, 24, 36 and 48 months from the first dose of the vaccine
2. HPV 16/18 antibody geometric mean titres (GMTs) induced by the different dose regimes at 7, 12, 24, 36 and 48 months
3. Relative HPV 6/11 type specific immune response in the different regimens in a sample of girls
4. The relative protection in terms of frequency of incident as well as persistent (12-month definition) HPV 16 and 18 infection
5. Frequency of incident infection by other non-targeted high-risk HPV types. Initial follow-up: 5 years. Extended follow-up: 15 years.
6. HPV 16- and 18-associated CIN 2-3, adenocarcinoma in-situ and invasive cancer following the two different dose regimes. Initial follow-up: 5 years. Extended follow-up: 15 years.
7. CIN and invasive cancer associated with non-included HPV types in the two study groups. Initial follow-up: 5 years. Extended follow-up: 15 years.

## **Secondary outcome measures**

No secondary outcome measures

## **Overall study start date**

01/06/2008

## **Completion date**

31/05/2013

# **Eligibility**

## **Key inclusion criteria**

1. Apparently healthy, ambulant, unmarried girls aged 10 - 18 years and with intact uterus
2. Resident in the villages chosen for the study

## **Participant type(s)**

Healthy volunteer

## **Age group**

Child

## **Lower age limit**

10 Years

## **Upper age limit**

18 Years

## **Sex**

Female

**Target number of participants**

16,000

**Key exclusion criteria**

Girls with any severe and/or debilitating illness

**Date of first enrolment**

01/06/2008

**Date of final enrolment**

11/04/2012

**Locations****Countries of recruitment**

India

**Study participating centre**

-

-

India

-

**Sponsor information****Organisation**

International Agency for Research on Cancer (IARC) (France)

**Sponsor details**

World Health Organization

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**Sponsor type**

Government

**Website**

<http://screening.iarc.fr>

**ROR**

<https://ror.org/00v452281>

# Funder(s)

## Funder type

Research organisation

## Funder Name

Bill and Melinda Gates Foundation (USA) - through the International Agency for Research on Cancer (IARC), World Health Organization (France)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/01/2016		Yes	No
<a href="#">Results article</a>	early results	06/08/2018		Yes	No
<a href="#">Results article</a>		08/10/2021	12/10/2021	Yes	No