

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Rengaswamy Sankaranarayanan

Contact details
150 Cours Albert Thomas
Lyon
France
69372 Cedex 08
+33 (0)4 72 73 85 14
sankar@iarc.fr

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

150 cours Albert Thomas

Lyon

France

69372 cedex 08

+33 (0)4 72 73 85 14

sankar@iarc.fr

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?
Results article	results	01/01/2016		Yes	No
Results article	early results	06/08/2018		Yes	No
Results article		08/10/2021	12/10/2021	Yes	No