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

Submission date 17/03/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/06/2008	**Overall study status** Completed	
Last Edited 12/10/2021	**Condition category** Cancer	

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

ClinicalTrials.gov (NCT)
NCT00923702

Protocol serial number
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

Study type(s)
Prevention

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(s)
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.

Key secondary outcome(s))
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
10 years

Upper age limit
18 years

Sex
Female

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)

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes