

Clinical trial of qHPV vaccine in HIV positive Men who have sex with men

Submission date 21/06/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/08/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/09/2023	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

As HIV-infected patients are living longer, non-AIDS-defining cancers (cancers which do not indicate the development of AIDS) are becoming much more common. Anal squamous cell carcinoma (ASCC) is one of the most common non-AIDS-defining cancers found in men who have sex with men (MSM). Around 90% of cases happen in individuals with a human papilloma virus (HPV) infection, the lesions (wounds) of which in the anal canal (back passage) are considered to increase risk of developing ASCC. One possible way to address this is to prevent HPV infections using the HPV vaccine. The aim of this study is to find out whether the HPV vaccine (qHPV) can help prevent the development of lesions in the anus that could lead to anal cancer.

Who can participate?

HIV positive adult MSM who have an anal infection caused by HPV.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive injections of the qHPV vaccine into their shoulder muscle (deltoid muscle) at the start of the study and then three and six months later. Those in the second group receive placebo (dummy) injections into their shoulder muscle (deltoid muscle) at the start of the study and then three and six months later. For all participants, the injections are in the same arm each time.

Participants undergo a scan of their anal canal to see whether there are any lesions so that the effectiveness of the vaccine can be assessed at the start of the study and then after 12, 24, 36 and 48 months. At the start of the study and then two and six months after each vaccination, participants complete a questionnaire about any side effects they have experienced as well as providing a blood sample.

What are the possible benefits and risks of participating?

Participants benefit from receiving screening, diagnosis and treatment of their HPV infection. Those who receive the qHPV vaccine could also benefit from continued protection against HPC infections and associated lesions which could develop into ASCC. There are no notable risks involved with participating in the study.

Where is the study run from?
University Hospital Virgen de las Nieves (Spain)

When is the study starting and how long is it expected to run for?
November 2011 to May 2017

Who is funding the study?
Progress and Health Foundation, Ministry of Health and Social Welfare (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PI-0619-2001 FPyS

Study information

Scientific Title

Efectiveness of the quadrivalent human papillomavirus (qHPV) vaccine in HIV-positive Spanish men having sex with men (MSM): a double-blind randomised clinical trial

Study objectives

The tetravalent vaccine of HPV administered to patients MSM infected with HIV, not colonized by the serotypes administered in the vaccine, will produce a reduction in the incidence and progression of dysplastic lesions (AIN, carcinoma) of the anal mucosa, which will modify the protocols of screening of lesions and an improvement in the quality and expectations of these patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Comité de ética de la investigación de centro Granada, 26/03/2012

Study design

Double-blind parallel-group randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

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

Anal cancer related with HPV and HIV positive MSM

Interventions

Participants are randomised to one of two groups using Epidat 3.1 software:

Vaccine group: Participants receive injections of 0.5ml Quadrivalent (HPVs 6/11/16/18) vaccine into the deltoid muscle at the baseline, 3 and 6 month study visits. All doses are completed in the same arm.

Placebo group: Participants receive injections of 0.5ml placebo into the deltoid muscle at the baseline, 3 and 6 month study visits. All doses are completed in the same arm.

Follow up for all participants (at 12, 24, 36 and 48 months) involves the recording of clinical-epidemiological variables, blood analyses (full blood haemogram and blood chemistry analytes

were measured, together with CD4, CD8 lymphocytes counts, and HIV viral load (VL)), PCR of the HPV and anal cytology, high-resolution anoscopy (HRA), and testing for antibodies against the 4 genotypes of the qHPV vaccine.

Intervention Type

Biological/Vaccine

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Not provided at time of registration

Primary outcome measure

Efficacy of the qHPV vaccine is assessed through the development of HSIL or anal cancer in anal mucosa using high resolution anoscopy at baseline and 48 months.

Secondary outcome measures

1. Clearance of HPV genotypes in anal canal mucosa after vaccination is measured using PCR at baseline, 12, 24, 36 and 48 months
2. Prevalence of high squamous intraepithelial lesion (HSIL) and HR-HPV in the anal mucosa is measured using high resolution anoscopy at baseline, 12, 24, 36 and 48 months
3. The seroconversion to the four serotypes of HPV used after vaccination is measured using PCR at baseline, 12, 24, 36 and 48 months
4. Adverse effects after vaccination are measured using a purpose build questionnaire (including questions about pain, nausea, diarrhoea, rash, abdominal pain, pain at injection site) and blood testing (to determine if there are any kidney, liver, or muscle effects) at baseline, 2 and 6 months after each vaccination

Overall study start date

30/11/2011

Completion date

12/05/2017

Eligibility

Key inclusion criteria

1. HIV-positive MSM patients
2. >18 years of age
3. Those who, at the time of inclusion into the study, had not been infected simultaneously by the 4 genotypes of HPV that the quadrivalent vaccine addresses
4. Patients who had high-resolution anoscopy (HRA) screening for inclusion are normal or had only condylomas and/or low squamous intraepithelial lesion (LSIL) in anal biopsy

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

Based on our own data, 67.2% of HIV MSM patients have a pathological anal biopsy and, of these, 29.8% have HSIL (\geq AIN2) with a rate of infection by high-risk genotypes of 74.2% [29]. To demonstrate a reduction of at least 34% with the administration of the qHPV vaccine, with a statistical power of 98% and a level of significance of 5%, it is necessary to include 60 patients per group.

Key exclusion criteria

1. HIV positive MSM (Men Who Have Sex with Men)
2. Simultaneous anal infection caused by the 4 genotypes addressed by the vaccine, or at least HPV16
3. Aged 18 years and over
4. Active opportunist infection at the time of recruitment into the study
5. Patients who, in screening anoscopy had HSIL, or ASCC or having received treatment for these lesions
6. History of allergy to aluminium and/or yeast extract excipient

Date of first enrolment

15/05/2012

Date of final enrolment

15/05/2014

Locations**Countries of recruitment**

Spain

Study participating centre

University Hospital Virgen de las Nieves

Av de las fuerzas armadas nº4

Granada

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Sponsor information**Organisation**

Fundacion Progreso Y Salud, Consejeria De Salud Y Bienestar Social (Progress and Health Foundation, Ministry of Health and Social Welfare)

Sponsor details

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Sponsor type

Government

Website

<http://fps2.junta-andalucia.es/fundacionprogresoysalud/es>

ROR

<https://ror.org/0048t7e91>

Funder(s)**Funder type**

Government

Funder Name

Fundacion Progreso Y Salud, Consejeria De Salud Y Bienestar Social (Progress and Health Foundation, Ministry of Health and Social Welfare)

Results and Publications**Publication and dissemination plan**

Planned publication of study results in a peer-reviewed journal.

Intention to publish date

31/12/2016

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/07/2017		Yes	No
Results article	results	18/07/2017		Yes	No
Results article		20/01/2021	12/09/2023	Yes	No