

Urban community randomised trial for prevention of sexually transmitted diseases

Submission date
22/07/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
22/07/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
06/02/2015

Condition category
Urological and Genital Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.proyectopreven.org/index.php?lang=en>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

059131

Study information

Scientific Title

An urban community randomised trial of a multicomponent intervention for the prevention of sexually transmitted disease in female sex workers and the general population

Acronym

PREVEN

Study objectives

We aim to:

1. Determine the impact of a hybrid intervention on:
 - 1.1. Prevalence of gonococcal, chlamydial, and trichomonal infection and syphilis seroreactivity in high-risk Female Sex Workers (FSW), bridging groups of clients of FSW, and the lower-risk young adult general population
 - 1.2. The antimicrobial susceptibility and virulence-associated phenotypes of *N. gonorrhoeae*
2. Develop and employ mathematical models of gonorrhoea, chlamydial infection, syphilis and trichomoniasis to explain the observed impact of the interventions, and facilitate transfer of the intervention to other locations

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Universidad Peruana Cayetano Heredia, 07/12/1999, ref: #99084
2. University of Washington, 25/07/2000, ref: #99-2288
3. Naval Medical Research Center Detachment, 19/09/2002, ref: DOD#31556

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Sexually transmitted disease prevention

Interventions

Using data from a baseline survey in 24 Peruvian cities with populations more than 50,000, 20 cities were selected for the trial and placed into matched pairs based on region (coastal, jungle or Andean), size and STD prevalence. The pairs were then randomised into control or intervention groups, with the latter receiving a two-year hybrid intervention of:

1. Strengthened syndromic management through a network of physicians and pharmacists
2. STD screening and treatment of FSW
3. Social marketing of condoms

At the end of the two-year intervention, FSW and the young adult general population in all 20 cities will be surveyed again to evaluate its impact.

The anticipated end date of this trial has been extended to the 31st December 2006. The previous anticipated end date was 31/12/2005.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Gonorrhoea, chlamydia, trichomonas, bacterial vaginosis, syphilis and human immunodeficiency virus (HIV) infection
2. Demographic and behavioural information regarding sexual history and risk behaviours

Secondary outcome measures

No secondary outcome measures

Overall study start date

24/08/2002

Completion date

31/12/2006

Eligibility**Key inclusion criteria**

1. General population survey: one adult per household ages 18 to 29 years, either sex
2. FSW: willing to participate
3. Clients of FSW: sex with a commercial sex worker

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

20 cities

Key exclusion criteria

1. General population survey: over 29 years old
2. All surveys: under 18 years old

Date of first enrolment

24/08/2002

Date of final enrolment

31/12/2006

Locations**Countries of recruitment**

Peru

United States of America

Study participating centre

University of Washington

Seattle, WA

United States of America

98104

Sponsor information**Organisation**

University of Washington (USA)

Sponsor details

Center for AIDS and STD

325 9th Avenue, Box

Seattle, WA

United States of America

98104

Sponsor type

University/education

Website

<http://www.washington.edu/>

ROR

<https://ror.org/00cvxb145>

Funder(s)

Funder type

Charity

Funder Name

Wellcome Trust

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

United Kingdom

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	24/03/2012		Yes	No
Results article	results	01/10/2012		Yes	No

