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The B-VAX Project

Submission date
27/08/2012

Recruitment status
No longer recruiting

Registration date
14/09/2012

Overall study status
Completed

Last Edited
04/08/2016

Condition category
Infections and Infestations

- [ ] Prospectively registered
- [ ] Protocol
- [ ] Statistical analysis plan
- [ ] Results
- [ ] Individual participant data
- [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The hepatitis B virus (HBV) is the leading cause of liver cancer and the tenth leading cause of death worldwide. People who inject drugs (PWID) are at risk of hepatitis virus infection through both unsafe injecting and unsafe sexual activity. The risk of developing liver disease is greater for people infected with both the hepatitis C and B virus, resulting in a high cost to the community in terms of future health care. Despite the availability of an effective HBV vaccine, research in Australia has demonstrated that a considerable proportion of people who inject drugs remain unvaccinated and are at risk of infection. For various complex social reasons many of these participants are not linked in with primary health or mainstream health services. New ways of delivering health services such as HBV vaccination are required to reach this group. HBV vaccination will reduce future disease burden including transmission to the wider community, and reduce the associated healthcare costs. Recent studies offering motivational incentives to people who inject drugs to complete HBV vaccination programs have achieved promising results with high completion rates. The aim of this study is to
evaluate the effectiveness of an outreach model increase HBV vaccination coverage among people who inject drugs. We will also measure the effectiveness of the standard and opportunistic accelerated vaccination schedules.

Who can participate?
People who inject drugs who are at risk of contracting HBV (or those not already immune or infected), identified from other Burnet Institute studies

What does the study involve?
Participants receive an initial vaccination, complete a brief questionnaire, and are then randomly allocated into one of the two groups. One group receive the standard vaccine schedule currently used by the Australian National Immunisation Program, where the vaccine is given to them at 0, 1 and 6 months. The other group receive the opportunistic accelerated vaccine schedule, where the vaccine is given to them opportunistically 'in the field' at a minimum of 0, 7 and 21 day intervals, with the option of a 12-month booster dose if the participants have not yet had an adequate immune response. Participants are followed-up by the project nurse to encourage completion of the vaccine course, and are paid a small motivational incentive after each contact. Blood samples are taken after each vaccination and six weeks after the final vaccine in both schedules to determine the participants' immune response at each stage of the study. Participants are also surveyed about their knowledge of HBV, including transmission, prevention

and vaccination, to enable us to compare the characteristics of people who completed the vaccination course with those who did not, so that we know how best to shape and target future vaccination projects. Some of the participants are interviewed in depth to further explore the barriers to seeking and completing vaccination and the acceptability of the outreach model of vaccine delivery.

What are the possible benefits and risks of participating?
Potential benefits include receiving a complete course of HBV vaccination as well as confirmation as to whether or not the vaccine has been successful, and the opportunity to discuss any health queries or concerns with the nurse. Possible risks, side effects and discomforts of participation include minor bruising around the site from which blood is taken, which occurs in fewer than one in ten cases. Some people may feel faint when having blood taken and may occasionally faint. Rarely, there could be a minor infection or bleeding. If this happens, it can be easily treated. The HBV vaccine is a safe and effective vaccine, but side effects may include redness or pain at the site of injection, a low grade temperature, and an itchy rash.

Where is the study run from?
The Burnet Institute (Australia)

When is the study starting and how long is it expected to run for?
September 2012 to December 2013

Who is funding the study?
1. Burnet Institute Centre for Research Excellence into Injecting Drug Use (Australia)
2. The Burnet Institute MIX Study (Australia)

Who is the main contact?
1. Danielle Collins (dcollins@burnet.edu.au)
2. Peter Higgs (peterh@burnet.edu.au)

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Project 40/12

Study information

Scientific Title
The B- VAX Project: providing hepatitis B vaccinations through assertive outreach to people who inject drugs

Acronym
B-VAX

Study objectives
1. Increase Hepatitis B virus (HBV) vaccination coverage among participants of current Burnet Institute cohort studies of PWID
2. Investigate the feasibility and acceptability of providing HBV vaccination to PWID using an outreach model
3. Evaluate the effectiveness of the outreach model for HBV vaccination delivery, completion and HBV Surface antibody seroconversion
4. Measure the efficacy of the standard versus opportunistic accelerated schedule in terms of serological immune response and vaccination completion rates

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Alfred Hospital Ethics Committee, 03/07/2012, ref: 40/12

Study design
The B-VAX Project is a modified intention to treat randomised control trial and is a sub study within a longitudinal cohort study. The trial is a single-centre trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Hepatitis B virus (HBV)

Interventions
The intervention provided in this trial will be the administration of the Engerix-B adult formulation HBV vaccine adhering to one of two vaccine schedules. Participants will receive an initial vaccine and be randomised into one of the two 'arms' of the study after receiving their baseline vaccine.
Arm 1: Standard vaccine schedule with the vaccine administered at 0, 1 & 6 months.
Arm 2: Opportunistic accelerated vaccine schedule, vaccine administered opportunistically 'in the field' at a minimum of 0, 7 & 21 day intervals, with the option of a 12 month booster dose if the participants have not yet mounted an adequate immune response.
Serology testing for the anti-HBs will be taken after each vaccination to determine the participants immune response at each stage of the trial.

Intervention Type
Biological/Vaccine

Primary outcome measure
1. Increasing vaccine coverage amongst this cohort of people
2. Measuring vaccine course completion between the standard schedule and the the opportunistic accelerated schedule
3. Measuring immunological vaccine response between the standard schedule and the the opportunistic accelerated schedule

Secondary outcome measures
Assessing the acceptability and feasibility of an assertive outreach model of vaccine delivery

Overall study start date
01/09/2012

Completion date
01/12/2013

Eligibility

Key inclusion criteria
Participants who are at risk of contracting HBV (or those not already immune or infected), will be identified from existing Burnet Institute cohort studies and approached to participate.

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
150

Key exclusion criteria
Participants from Burnet Institute Cohort studies who are vaccinated or immune to HBV.

Date of first enrolment
01/09/2012

Date of final enrolment
01/12/2013

Locations

Countries of recruitment
Australia

Study participating centre
The Burnet Institute
Melbourne
Australia
3001

Sponsor information

Organisation
The Burnet Institute (Australia)

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Sponsor type
Research organisation

Website
http://www.burnet.edu.au/

ROR
https://ror.org/05ktbsm52

Funder(s)

Funder type
Research organisation

Funder Name
Burnet Institute Centre for Research Excellence into Injecting Drug Use (Australia)

Funder Name
The Burnet Institute MIX Study (Australia)

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