

Dried blood spot testing in UK prisons

Submission date 11/03/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 18/05/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/07/2014	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

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

Version 1

Study information

Scientific Title

Cluster randomised controlled trial of dried blood spot testing in UK prisons

Study objectives

An intervention using dried blood spot testing for blood borne viruses will increase the blood borne viral diagnostic testing rate in prisons. This is defined as the proportion of the monthly prison throughput who take up the offer of a diagnostic test for blood borne viral infection (either venepuncture pre-intervention or DBS post intervention).

Ethics approval required

Old ethics approval format

Ethics approval(s)

10/MRE09/23 Research ethics committee for Wales

It was noted that as this research will not be taking place within the NHS and is not a clinical trial of a medicinal product for human use, it falls outside the remit of Research Ethics Committees as set out in the Governance Arrangements for NHS Research Ethics Committees (GAFREC). The members present agreed that as this study fallen within their remit it would have been given a favourable opinion. The National Offender Management system (NOMS) and Ministry of Justice were also contacted; both bodies were satisfied that the study did not need further consideration by themselves.

Study design

Stepped wedge cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied

Blood borne virus infection [Hepatitis C, Hepatitis B, Human immunodeficiency virus (HIV)]

Interventions

1. Dried blood spot testing (DBS) for blood borne viral infection
2. Comparing DBS against standard venepuncture based testing
3. The planned intervention is the opt-in offer of DBS testing for blood borne viruses (BBV) infection to all inmates at reception
4. The test will be offered by clinically trained prison health staff (either prison doctors or senior nursing staff) in a confidential manner
5. Results will likewise be fed back to inmates requesting diagnostic testing in a manner that ensures both confidentiality and prevents deductive disclosure. Intervention thus the training of prison healthcare staff in BBV diagnostic testing and the dried blood spot test

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Change in blood borne viral diagnostic testing rate in prisons with introduction of DBS

Secondary outcome measures

Epidemiological data on prison disease prevalence for ongoing mathematical modelling research

Overall study start date

07/04/2011

Completion date

07/04/2012

Eligibility**Key inclusion criteria**

Five UK prisons - all inmates offered intervention

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Prison throughput within study time period for each of five prisons recruited to the study

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

07/04/2011

Date of final enrolment

07/04/2012

Locations**Countries of recruitment**

United Kingdom

Wales

Study participating centre
Micobiology dept
Bangor
United Kingdom
LL57 2PW

Sponsor information

Organisation
Public Health Wales (UK)

Sponsor details
Health Protection
Temple of Peace and Health
Cathays Park
Cardiff
United Kingdom
CF10 3NW

Sponsor type
Government

Website
<http://www.wales.nhs.uk/sitesplus/888/>

ROR
<https://ror.org/00265c946>

Funder(s)

Funder type
Government

Funder Name
Public Health Wales (UK)

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	01/04/2015		Yes	No