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Different approaches to partner notification in primary care

Submission date
22/02/2010

Recruitment status
No longer recruiting

Registration date
18/03/2010

Overall study status
Completed

Last Edited
10/05/2016

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Increasing numbers of patients are diagnosed with sexually transmitted infections (STIs) in their GP surgery. This study is concerned with finding out the best way to enable treatment for the sexual partners of individuals diagnosed with STIs in their GP practice. This is called "partner notification". Treatment of partners is important for two reasons - to protect the original patient from reinfection, and to prevent the further spread of infection by infected partner(s). We will compare three different approaches to partner treatment: patient referral, contract referral and provider referral. Patient referral is where patients are simply given information and asked to tell their partner about the problem and the need to be treated. Contract referral is where, in addition to patient referral, patients will be asked to agree to a specialist health adviser (contact tracing expert) to inform their partner(s) if this has not been done after a period of time (say, a week). Provider referral is where, in addition to patient referral, patients will be offered the option of a specialist health adviser contacting their partner(s) at the time of diagnosis.

Who can participate?
Patients over the age of 16 diagnosed with sexually transmitted infections at participating GP practices

What does the study involve?
Participating GP practices are randomly allocated into three groups, and trained to manage all their patients according to one of the above approaches. We measure how well these three approaches to partner notification work by comparing how many partners get treated. We also measure how many of the original patients are still infected in each group, as this is also a good measure of partner notification. We also compare the cost effectiveness of the three approaches.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Brighton and Sussex Medical School (UK)

When is the study starting and how long is it expected to run for?
May 2010 to April 2013

Who is funding the study?
Health Technology Assessment (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 07/43/01

Study information

Scientific Title
The relative clinical and cost-effectiveness of three contrasting approaches to partner notification for curable sexually transmitted infections (STIs): a cluster randomised trial in primary care

Study objectives

Increasing numbers of patients are diagnosed with sexually transmitted infections (STIs) in their GP surgery. We want to find out the best way to arrange treatment for the sexual partners of individuals who are diagnosed with STIs in their GP practice (partner notification). Treatment of partners is important for two reasons; to protect the original patient from re-infection, and to prevent the further spread of infection. We will compare three different approaches:
1. Patient referral
2. Contract referral
3. Provider referral

GP practices will be randomly split into three groups, and will manage all their patients according to ONE approach. We will measure how well these three approaches work, by comparing how many partners get treated and how many of the original patients are still infected in each group. In addition, we will do an economic study of the cost-effectiveness of each approach, and compare them.

We are testing the following null hypothesis:
Provider referral and contract referral offer no advantage over patient referral in partner notification for curable sexually transmitted infections in the primary care setting.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/074301
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0003/51843/PRO-07-43-01.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Brighton West Research Ethics Committee, 14/10/2009, ref: 09/H111/49

Study design
Interventional multicentre cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

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
Sexually transmitted infections (STIs)

Interventions
We will compare three different interventions in partner treatment:
1. Patient referral: patients are given information about their infection, and asked to tell their partner about the problem and the need to be treated
2. Contract referral: in addition to point 1 above, patients will be asked to agree to a specialist health adviser (contact tracing expert) to inform partner(s) if this has not been done after an agreed period of time (usually two days)
3. Provider referral: in addition to point 1 above, patients will be asked to agree to a specialist health adviser contacting one or more of their partner(s) at the time of diagnosis

Treatment is a communication process without a defined duration. Follow up will be 10 - 12 weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Number of main partners per index patient treated for chlamydia and/or gonorrhoea /nonspecific urethritis/pelvic inflammatory disease
2. Proportion of index patients testing negative for the relevant STI at 3 months

Secondary outcome measures
1. Number of partners per index patient presenting for treatment
2. Proportion of index patients having at least one partner treated
3. Number of main, casual and ex-partners per index patient tested for the relevant STI
4. Number of main, casual and ex-partners testing positive for the relevant STI
5. Number of index patients tested for HIV by 3 months
6. Number of current partners tested for HIV by 3 months
7. Time to definitive treatment of index patient for the relevant STI
8. Time to definitive treatment of current partner for the relevant STI
9. Uptake by index patients of "contract" and "provider" referral for one or more partners, within the relevant randomised groups
10. Patient-related factors impacting on partner notification or STI disclosure to main, casual and ex-partners

An important secondary aim is to identify what patient-related or psychological factors impact on disclosure.

Overall study start date
01/05/2010

Completion date
30/04/2013

Eligibility

Key inclusion criteria

Practices:
1. Practices from the MRC General Practice Research Framework (GPRF), the South East Primary Care Research Network (PCRN-SE) or the Primary Care Research Network Greater London (PCRN-GL)
2. Registered populations of 5000 or more
3. A maximum of six practices considering themselves as "student health centres" will be recruited, and no more than four regarding themselves as running "locally enhanced services for sexual health"

Individuals:
1. Belonging to the target population above
2. Over the age of 16 years (either sex) at the time of first attendance for this problem, or of screening for chlamydia (NB patients will be eligible if they refuse to communicate with partners, given the objectives of the study)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
3300 individuals with an STI, from 66 practices

Key exclusion criteria
Patients:
1. Learning difficulties
2. Unable to read trial materials after discussion with clinical staff
3. No means of communication acceptable to the patient for him/herself

Date of first enrolment
01/05/2010

Date of final enrolment
30/04/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Brighton and Sussex Medical School
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Sponsor information

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University of Sussex (UK)

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Sponsor type
University/education

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ROR
https://ror.org/00ayhx656

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

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	01/01/2015		Yes	No