ISRCTN27312734 https://doi.org/10.1186/ISRCTN27312734

Does Accelerated Partner Therapy" (two new models of care which emphasise rapid treatment and which will be different from traditional clinic–based methods) reduce delays in the assessment and treatment of sexual partners of people with bacterial sexually transmitted infections

Submission date
30/07/2012

Recruitment status
No longer recruiting

Registration date
30/07/2012

Overall study status
Completed

Last Edited
14/01/2016

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Rates of sexually transmitted infections (STIs) in the UK continue to rise each year. Successful control of STIs relies on reducing the spread of infection in the community. One way of doing this is to cut down the length of time an individual carries the infection before seeking treatment. Partner notification (PN) aims to do this by informing the infected person's sexual partners of the possibility of exposure, offering diagnosis and treatment, and providing advice about preventing future infection. However, the effectiveness of PN as it is currently practised in the UK is doubtful, and many sexual health/Genito Urinary Medicine (GUM) clinics struggle to reach national targets. We do not know the best ways of carrying out PN. The current system relies on the infected person informing their partners and advising them to attend a sexual health clinic or their GP for testing and treatment. This is known as patient referral. However, many sexual contacts are reluctant to come forward and new methods need to be tested. We believe that new methods of PN, which include assessment of the sexual partner by a healthcare professional but do not require clinic attendance, will be key to improving PN in the UK. We call these methods Accelerated Partner Therapy (APT). The aim of this study is to determine the acceptability and feasibility of two new models of APT for STI patients in UK clinics. We will also obtain evidence of the effectiveness of APT as compared with routine PN practice and find out for whom APT is best suited.

Who can participate?
Patients who are 16 and older and have tested positive for Chlamydia and/or Gonorrhoea (men and women), and men who have been diagnosed with non-gonococcal urethritis, and have at least one contactable partner.

What does the study involve?
Sexual health advisers in the participating clinics offer eligible patients a choice of three PN strategies:
1. APT Hotline (patient's sex partner calls the APT hotline for a telephone consultation with a clinic health adviser/nurse practitioner)
2. APT Pharmacy (patient's sex partner attends pharmacy for consultation)
3. Standard PN using patient referral (patient advises their sex partner to attend a sexual health clinic or their GP)
We then compare the outcomes for the APT interventions with standard PN. It is important to give the patient a choice because APT may be more effective if offered as part of a 'menu' of PN options, and so we can determine for whom APT is best suited. If APT is successful, it would also be offered as a choice alongside patient referral. Patients who test positive for Gonorrhoea are given antibiotics. Treatment packs include information sheets on the relevant antibiotics, including drug interactions and possible side effects. A study hotline number is also prominently displayed in each pack, which patients can use to obtain advice or support.

What are the possible benefits and risks of participating?
If the approach we propose is successful, it could enhance the provision of care to partners of patients with STIs, particularly those less likely to access existing services. The net result would be a decrease in STIs in the community and fewer re-infections. Together this would reduce the complications of STIs, such as infertility and pelvic inflammatory disease and their costly health consequences.

Where is the study run from?
Barts Sexual Health Centre in London and The Milne Centre in Bristol (UK).

When is the study starting and how long is it expected to run for?
November 2007 to July 2008

Who is funding the study?
Medical Research Council (MRC) (UK)

Who is the main contact?
Dr Lorna Sutcliffe (L.j.sutcliffe@qmul.ac.uk)
Dr Claudia Estcourt (c.s.estcourt@qmul.ac.uk)

Study website
http://www.aptresearch.co.uk/

Contact information

Type(s)
Scientific

Contact name
Dr Lorna Sutcliffe

Contact details
St Bartholomew's Hospital
Centre for Infectious Disease: Sexual Health & HIV
Barts & The London School of Medicine & Dentistry
Barts Sexual Health Centre,
Kenton & Lucas Wing,
St. Bartholomews Hospital
West Smithfield
London
United Kingdom
EC1A 7BE
-
l.j.sutcliffe@qmul.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2564

Study information

Scientific Title
Can Accelerated Partner Therapy (APT) improve outcomes of partner notification? A feasibility study and exploratory trial

Acronym
APT

Study objectives
We propose to develop two models of Accelerated partner Therapy (APT) and then to determine acceptability and feasibility of these two models of APT for index patients with chlamydia and /or gonorrhoea and/or non gonoccocal urethritis in the UK clinics and obtain preliminary data on effectiveness of APT as compared with routine PN.

Specific objectives:
1. To develop through qualitative research, consumer and stakeholder consultation, a feasible, replicable intervention for
delivering APT in UK GUM clinics
2. To determine the acceptability and feasibility of APT to clinic attenders, their sexual contacts and staff
3. To obtain preliminary evidence of effectiveness of APT compared with routine PN by undertaking an exploratory trial in two contrasting GUM services
4. To obtain cost data for APT strategies to use in preliminary economic evaluation based on restricted outcomes such as cost per partner treated

5. To develop a protocol for a formal randomised controlled trial (RCT) comparing the outcomes of APT with standard PN.
Interventions that involve changing health services are complex, so detailed development work is needed to define
appropriate study areas, study populations and potential interventions. This project comprises the first three stages of the UK Medical Research Council (MRC) Framework for Development of Randomised Controlled trials for Complex Interventions to Improve Health. The project will take place in two contrasting areas in England; Bristol, in the South West, which includes both rural and urban areas, and in inner city London.

More details can be found at http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=2564

Ethics approval required
Old ethics approval format

Ethics approval(s)
East London Research Ethics Committee 1, 26/11/2010, ref: 06/Q0101/3

Study design
Non-randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

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
Topic: Infection; Subtopic: Infection (all Subtopics); Disease: Infectious diseases and microbiology

Interventions
APT Hotline: Index diagnosed, treated & given APT PIN
1. Sex partner calls APT hotline for telephone consultation with clinic Health adviser/Nurse practitioner
2. Index takes or Sex partner collects APT Pack from clinic reception
3. Sex partner attends clinic for Human immunodeficiency virus (HIV) & test at later stage
4. Index & contact follow up call

APT Pharmacy, Index diagnosed, treated & given APT PIN
1. Sex partner attends pharmacy for consultation: trained pharmacist under Patient Group Directions (PGD) gives APT Pack

2. Sex partner attends clinic for HIV test at later stage
3. Index & contact follow up call

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Proportion of index patients having at least one partner treated 4-6 weeks after intial diagnosis

Secondary outcome measures
1. Proportion of regular partners treated
2. Number of contacts treated per index patient

Overall study start date
01/11/2007

Completion date
01/07/2008

Eligibility

Key inclusion criteria
1. Index patients who are 16 years and older
2. Have tested positive for Chlamydia and/or Gonorrhoea (men and women)
3. Men who have been diagnosed with non-gonococcal urethritis (NGU) and have at least one contactable partner

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 300; UK Sample Size: 300

Key exclusion criteria
Will be determined by a suitabily qualified health professional are:
1. Pregnancy
2. Symptoms of complicated infection, allergy or contraindications to Azithromycin and or Cefixime

3. Inability to read English
4. An inability to understand instructions and give consent
5. Co-existent infection with syphilis and/or HIV as these cases require different investigation and management

Date of first enrolment
01/11/2007

Date of final enrolment
01/07/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Bartholomew's Hospital
London
United Kingdom
EC1A 7BE

Sponsor information

Organisation
Barts and The London Trust (UK)

Sponsor details
St Bartholomew's Hospital
West Smithfield City of London
London
England
United Kingdom
EC1A 7BE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

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	01/02/2012		Yes	No