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The impact of providing post-abortion contraceptive support

Submission date
31/10/2011

Recruitment status
No longer recruiting

Registration date
31/10/2011

Overall study status
Completed

Last Edited
30/07/2019

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Women resident in the boroughs of Lambeth, Southwark and Lewisham experience some of the highest rates of unplanned pregnancies, abortions and repeat abortions in the UK. This situation could be due to poor uptake and continuation of effective contraception after abortion. We believe that there is a gap between provision of abortion care and effective post-abortion care which needs to be improved. Our study is designed to see if specialist support provided to women during the few months following an abortion to help them with their contraception could reduce unplanned pregnancies and repeat abortions in the near future. The aim of this study is to see if specialist support after abortion helps women with their use of contraception to prevent unplanned pregnancies in future.

Who can participate?
Patients undergoing abortion under the National Health Service (NHS) in Lambeth, Southwark and Lewisham (London, UK).

What does the study involve?
Participants provide personal information (e.g. date of birth, ethnicity, postcode, education, relationship status, number of previous pregnancies, contraception used) and are randomly allocated to either the standard care group or the specialist support group. For participants in the standard care group, follow-up care after abortion remains the same as current standard practice. They are given full information about contraceptive choices available and where to access them. Participants in the specialist support group, in addition to standard contraceptive care, are offered a consultation with a contraception specialist doctor/nurse from King's College Hospital. At 2-4 weeks after the abortion participants attend a telephone or face-to-face clinic appointment lasting about 30 minutes. During this consultation, the specialist helps participants to choose a contraceptive method that suits them or helps them with any problems they have with a contraceptive method they are already using. 3 months after the abortion, participants receive a telephone call from the research doctor/nurse lasting about 15 minutes to address any problems they may have with their chosen method of contraception and offer help with changing the method if they wish. Both groups receive a telephone follow-up lasting about 15

minutes with the research doctor/nurse 6 months after their abortion to see how they are doing with their contraception. Routinely collected data on abortions is also studied to see if there are any repeat abortions in the study participants during the 2-year period following the abortion.

What are the possible benefits and risks of participating?
Participants in the specialist support group have the opportunity to have a specialist nurse contact them to discuss contraception. It is hoped that this will be helpful to everyone, as participants may want to ask her questions and receive advice on where they can go to get contraception, and in some case be referred to a specialist doctor. For participants in the standard care group the benefits are less, but they have the opportunity to speak with the specialist nurse at 6 months after the abortion. Participants are asked questions about their contraceptive method and have the opportunity to ask questions to the specialist nurse yourself if they wish. This study will help to find out whether specialist support helps women to effectively use contraception and prevent further unplanned pregnancy. If such follow-up specialist support proves to be beneficial, this could be made standard practice. There have been no risks identified from participating in this study. All information which is collected during the course of the research is kept strictly confidential. However, there will be limits to confidentiality should something of concern be disclosed. The data collected for the study will only be looked at by authorised persons from the research team.

Where is the study run from?
Camberwell Sexual Health Centre (UK)

When is the study starting and how long is it expected to run for?
October 2011 to July 2015

Who is funding the study?
London Sexual Health Programme (UK)

Who is the main contact?
Dr Usha Kumar
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Contact information

Type(s)
Scientific

Contact name
Dr Usha Kumar

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10663

Study information

Scientific Title
Randomised controlled study of the impact of provision of follow-up contraceptive support to women who have had an abortion

Acronym
PACS (Post-Abortion Contraception Support)

Study objectives
Compare the effect of a specialist intervention to provide contraceptive support following abortion with that of the existing arrangement of ad-hoc follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC, 22/03/2011, ref: 11/H0709/1

Study design
Randomised interventional 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Reproductive health

Interventions
The intervention will be in the form of a structured follow-up consultation with a specialist in a Reproductive and Sexual Health service either by telephone or a face-to-face clinic appointment depending on patient preference, 2-4 weeks after the abortion to discuss contraception and a telephone follow-up 3 months after to provide further contraceptive support. Women will be offered the opportunity to bring their male partners to the follow-up appointment if they wish for participation in contraceptive counseling. Those who Do Not Attend (DNA) their 2-4 week appointment will be contacted by telephone to identify reason for DNA and will be offered another suitable appointment for a telephone consultation or face-to-face clinic appointment with the specialist. We hope that this intervention will facilitate uptake of reliable methods of contraception and their continuation, ultimately intended to lower repeat abortion rates.

UK Sample Size: 743; However, recruitment was slower than anticipated and ceased at 569 patients on 28/02/2013 due to withdrawal of two recruitment centres from the study.

Based on abortion data for Lambeth, Southwark and Lewisham residents in 2009, there were 2885 NHS abortions at BPAS, 1725 at Marie Stopes International (MSI) and 748 in King's College Hospital. From this data, we can deduce the average of number of abortions at 3 months as: 721 (54%) abortions at BPAS, 431 (32%) at MSI and 187 (14%) at King's College Hospital with a total number of abortions for all three centres estimated as 1339.
Based on published papers (Schunmann et. al), there was 68% uptake of long-acting reversible contraception (LARC) or contraceptive pills at 4 months following abortion; we have assumed the same at 6 months post-abortion. 34.84% refused to participate in the above study; we have used 35% refusal to participate for sample size calculation. There was 61.5% follow-up rate at 4 months in the above study. We have used 60% follow-up rates at 6 months for sample size calculation.

Description: Specialist contraceptive follow-up support will be provided 2-4 weeks and 3 months post-abortion to patients randomised to the intervention arm. Both arms will be contacted at 6 months post-abortion to obtain information on contraceptive uptake and continuation.

Follow Up Length: Data on repeat abortion data at 1 and 2 years post-abortion will be obtained for all participants using data-linkage from routinely collected abortion data from Department of Health.

Intervention Type
Behavioural

Primary outcome measure
Six-month post-abortion contraceptive uptake and continuation

Secondary outcome measures
Repeat abortion at 1 and 2 years

Overall study start date
01/10/2011

Completion date

01/07/2015

Eligibility

Key inclusion criteria
Patients undergoing abortion under the National Health Service (NHS) in Lambeth, Southwark and Lewisham (London, UK) who have consented to participate in the study

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
569

Total final enrolment
569

Key exclusion criteria
1. Patients who do not speak English
2. Patients who will be leaving the country for 6 months after the abortion and hence will not be available for the follow-up appointments or telephone follow-ups
3. Patients who lack capacity to consent for themselves
4. Patients who attend for the pre-abortion consultation but do not go ahead with the abortion

Date of first enrolment
03/10/2011

Date of final enrolment
28/02/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Sexual Health
Camberwell Sexual Health Centre
King’s College Hospital NHS Foundation Trust
100 Denmark Hill

London
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SE5 9RS

Sponsor information

Organisation
King's College Hospital NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.kch.nhs.uk/

ROR
https://ror.org/01n0k5m85

Funder(s)

Funder type
Government

Funder Name
London Sexual Health Programme (UK)

Results and Publications

Publication and dissemination plan
Planned submission for publication in a high-impact peer-reviewed journal by November 2017.

Intention to publish date
01/11/2017

Individual participant data (IPD) sharing plan

Participant-level data is not expected to be made available due to patient confidentiality reasons. Data will be held with the principal investigator for the study.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/06/2019	30/07/2019	Yes	No