ISRCTN01846583 https://doi.org/10.1186/ISRCTN01846583

Integrating post-abortion family planning services into China's existing abortion services in hospital settings

Submission date
02/09/2014

Recruitment status
No longer recruiting

Registration date
23/10/2014

Overall study status
Completed

Last Edited
10/05/2021

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Women who repeatedly have abortions are at high risk of long-term physical and psychological harm, and this can result in heavy economic and social costs. In China, there are a large number of abortions primarily due to the lack, or failure of, contraception. Here, we want to integrate post-abortion family planning (FP) services with existing abortion services offered by hospitals in China and to see whether it results in fewer unintended pregnancies and repeated abortions.

Who can participate?
Hospitals in mainland China offering abortion services and that carry out an average of 200-800 abortions a month.

What does the study involve?
The hospitals are randomly allocated into one of three groups. Two of these groups are intervention groups. Relevant personnel at these hospitals are trained to provide individual counselling (both before and after abortion), offer modern contraceptive methods, follow up counselling and educational materials. The hospitals in the control group offer their normal abortion services. A total of 18,000 women seeking abortion take part in the study and are treated according to whether they are in a intervention group or control group hospital. They are all asked to complete questionnaire surveys before their abortion, after their abortion, 1 month later and then 6 months later. At the end of the study, we will look at how well the intervention performs using both quantitative and qualitative methods.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part, but there should be benefits for the future. The project will contribute to standardizing the post-abortion family planning services and to reducing the long-term costs related to abortion in China. The results of this research will also be of interest to other countries with high abortion rates. The participants do benefit from free access to contraception and guidance services , free information materials on post-abortion care and contraception and free contraceptives.

Where is the study run from?
Hospitals in mainland China.

When is study starting and how long is it expected to run for?
September 2014 to May 2015.

Who is funding the study?
European Commission (EC) under the Seventh Framework Programme (FP7) (Belgium)

Who is the main contact?
Professor Wei-Hong Zhang
weihong.zhang@ugent.be
Professor Marleen Temmerman
marleen.temmerman@ugent.be

Study website
http://www.inpacproject.eu

Contact information

Type(s)
Scientific

Contact name
Prof Wei-Hong Zhang

Contact details
International Centre for Reproductive Health
Ghent University
De Pintelaan 185 UZP114
Ghent
Belgium
9000
+32 (0)9 332 94 81
weihong.zhang@ugent.be

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Effect of Post-Abortion Family Planning services on contraceptive practices in China: a cluster randomized controlled trial

Acronym
INPAC

Study objectives
The integrating of post abortion family planning intervention packages might increase the contraceptive use after abortion, and reduce the rates of unintended pregnancy and repeated abortions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of University Hospital Ghent (ETHISCH COMITE Universitair Ziekenhuis, University Ghent); ref. B670201215002
2. Ethics Committee of National Research Institute for Family Planning, China; Ref. No.3 of 2014

Study design
Four-year open randomized controlled three-arm multi-site trial where the unit of randomization is the hospital

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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
Post-abortion contraception (or post-abortion family planning) services

Interventions
The trila is conducted in mainland China. There are two intervention groups and one control group (each 30 hospitals) allocated randomly.

Intervention package:
1. Training of service providers and managers
2. Providing relevant Information, Education and Communication (IEC) to women and their partners by abortion service providers
3. Providing individual counselling to women (and their partners) at pre- and post abortion by

abortion service providers
4. Offering modern contraceptive methods to the women immediately after the abortion
5. Continuous PAFP service/follow-up counselling
6. Incentive mechanism to service providers

The control group will keep the normal services without any project interventions.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Unintended pregnancies including clinical or self-reported at the time of follow-up interviews
2. Repeat induced abortions and ongoing pregnancies that women did not want to give birth to a baby among all follow-up women during the follow-up period
3. Use of modern contraceptive methods including OCP, IUDs, implants, male/female condoms, others barrier methods (such as diaphragms, the cervical cap and spermicides), emergency contraception, sterilization (male/female) during follow-up period

Measured using both quantitative and qualitative methods.

Secondary outcome measures
1. Immediate contraceptive uptake: including IUD, OCP, sterilization, injection, implant, etc.
2. Contraceptive practices: use of any contraceptive methods, including condom, natural methods (periodic abstinence or withdrawal), IUDs, OCP, EC, sterilization, injection, implants, diaphragm, spermicide, etc. during follow-up period
3. Consistent use, correct use, and both consistent and correct use of condom among condom users during the follow-up periods
4. Changes in knowledge and attitudes about the risk of unintended pregnancies
5. Morbidity/mortality related to abortion
6. Sexually transmitted infections (including HIV)
7. Satisfaction regarding abortion and family planning services
8. Post-abortion family planning services received during abortion services among all participants, including group education, individual counselling, free contraceptives and referral to other family planning services
9. Pregnancies among all follow-up women during the follow-up period
10. Reported direct cost related to the abortion

Overall study start date
01/08/2013

Completion date
31/12/2016

Eligibility

Key inclusion criteria
Hospital inclusion criteria was identified according to the situation analysis findings and Chinas current hospital settings:

1. Agreement with the randomized allocation
2. Average number of abortions per month between 200 to 800
3. Willing and able to carry out the intervention packages proposed by the study
4. Availability to collect data at three time-points
5. Consent given for involvement within an appropriate environment

Women will be eligible to be interviewed and followed-up if they seek abortion at participating hospitals and meet the following inclusion criteria (all women visiting the participating hospitals will receive normal services regardless of their participation conditions):
1. Unintended pregnancies seeking induced abortion
2. Gestation age less than 12 weeks
3. Aged 18 to 40 years
4. Sexually active women of childbearing potential and not planning to become pregnant during the study
5. No physical and mental problem that may affect subject enrolment or follow-up
6. Willing to give informed consent in writing
7. Willing and able to response the scheduled surveys and to comply with the study procedures

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
90 hospitals, 18,000 women

Total final enrolment
17235

Key exclusion criteria
Hospitals do not meet the above inclusion criteria will not be considered eligible to this study.
Exclusion criteria for women:
1. Intention to become pregnant during the study

Date of first enrolment
01/07/2014

Date of final enrolment
28/02/2016

Locations

Countries of recruitment

Belgium

China

Study participating centre
International Centre for Reproductive Health
Ghent
Belgium
9000

Sponsor information

Organisation
European Commission Seventh Framework (EC FP7) (Belgium)

Sponsor details
Directorate-General for Research & Innovation
E6
Brussels
Belgium
1049
+32 229 96211
lucia.bizonova@ec.europa.eu

Sponsor type
Government

Website
http://ec.europa.eu/research/index.cfm

ROR
https://ror.org/00k4n6c32

Funder(s)

Funder type
Government

Funder Name
European Commission

Alternative Name(s)

European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκής Επιτροπής, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságról, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
Planned dissemination of findings at national and international levels by participating in the scientific conferences and workshops and submit manuscript for publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to ongoing data clean and analysis.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		01/12/2017	10/05/2021	No	No
Protocol article			10/05/2021	Yes	No