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The effectiveness of bridging from emergency to regular contraception

Submission date
17/03/2017

Recruitment status
No longer recruiting

Registration date
20/03/2017

Overall study status
Completed

Last Edited
16/05/2023

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Emergency contraception (EC) is a tablet that can prevent pregnancy following unprotected sex. Most women in the UK go to a pharmacy for EC. It is important to start a regular method of contraception after EC, but most pharmacies cannot provide this without a prescription. This means that women must then go to a GP or a family planning clinic and some fall pregnant during this time. the aim of this study is to find out whether pharmacists should give a supply of the progestogen only pill (POP) along with EC to women as temporary contraception until they can get to a clinic. The POP is very safe with no serious risks. A smaller similar study showed that women who received the POP were likely to use it and more likely to be using contraception 6 weeks later than those who just got EC.

Who can participate?
Women aged 16 and over who attend a participating pharmacy for EC

What does the study involve?
Participating pharmacies are randomly allocated to give EC as usual, or to give the POP with the offer of rapid access to the local family planning clinic. Participating women are surveyed at 4 months about contraceptive use, and about any pregnancies they may have had. Women who received the POP are asked if they used it and/or attended the family planning clinic. In order to find out whether providing the POP prevents unintended pregnancies, with the participating women's permission, existing NHS databases are checked to see how many women in the study had an abortion within one year. Women, pharmacists and family planning clinic staff are also interviewed about how providing the POP/rapid access might work in everyday practice.

What are the possible benefits and risks of participating?
The information from this study will help to determine whether providing women with a temporary supply of POP along with help to get a quick appointment at a local sexual health clinic prevents more unintended pregnancies than just using EC alone. The POP is a very safe method of contraception and the POP used in the study is widely used, so no risks are expected.

Where is the study run from?
1. Community pharmacies in NHS Lothian & Chalmers Sexual Health Centre (UK)

2. Margaret Pyke Centre & participating community pharmacies (UK)
3. Kings College London Sexual Health Service & participating community pharmacies (UK)
4. Community pharmacies in NHS Tayside & Tayside Sexual Health Service (UK)

When is the study starting and how long is it expected to run for?
April 2017 to June 2020

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

Who is the main contact?
Prof. Sharon Cameron
Sharon.Cameron@ed.ac.uk or Bridge-IT@ed.ac.uk

Contact information

Type(s)
Public

Contact name
Prof Sharon Cameron

ORCID ID
https://orcid.org/0000-0002-1168-2276

Contact details
Chalmers Centre
Edinburgh
United Kingdom
EH3 9ES

Additional identifiers

Protocol serial number
HTA 15/113/01

Study information

Scientific Title
A randomised controlled trial to determine the effectiveness of bridging from emergency to regular contraception: the Bridge–it study

Study objectives
Provision of a ‘bridging' supply of the progestogen only pill plus an invitation for a rapid appointment at a local sexual health and reproductive health service to women at the time they present for emergency contraception (EC) at a community pharmacy, will be associated with higher uptake of effective contraception and fewer unintended pregnancies (and reduced abortion rates) compared to standard care alone (provision of EC and advice on commencing effective contraception after EC).

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Scotland REC 01, 27/06/2017, ref: 17/SS/0080

Study design
Cluster randomised controlled cross over trial

Primary study design
Interventional

Study type(s)
Prevention

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

Interventions
Current intervention as of 31/01/2019:
Community pharmacies will be cluster randomised to provide the intervention followed by a control phase (on a new group of women) or vice versa.

The planned intervention is a composite intervention consisting of 3 months of a progestogen only pill (POP) containing 75 mcg desogestrel and the offer to attend a local participating sexual and reproductive health (SRH) service to discuss and provide ongoing effective contraception.

Previous intervention:
Community pharmacies will be cluster randomised to provide the intervention followed by a control phase (on a new group of women) or vice versa. Computer generated cluster randomisation: a confidential list is generated made up of a random mix of permuted blocks of size 2, 4 and 6 (100 units) and then assigned the order by looking it up on the confidential list as new pharmacies join.

The planned intervention is a composite intervention consisting of 3 months of a progestogen only pill (POP) containing 75 mcg desogestrel and the offer to attend a local participating sexual and reproductive health (SRH) service to discuss and provide ongoing effective contraception.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 31/01/2019:
Effective contraception use (hormonal and intrauterine) determined by telephone contact (or survey) at 4 months.

Previous primary outcome measure:
1. Effective contraception use (hormonal and intrauterine) determined by telephone contact (or survey) at 4 months

2. Long acting reversible conraception (LARC) use, self reported at 4 months
3. Proportion of participants having undergone an abortion using record linkage from participants to national registries at 12 months

Key secondary outcome(s))
Current secondary outcome measures as of 31/01/2019:
1. Proportion having undergone an abortion at 12 months (Data linkage from Information Services Division (ISD Scotland) and Department of Health (DOH England) will provide the number of abortions occurring during the 12 month follow up period.)
2. To determine whether the intervention is cost effective to the NHS. (An economic evaluation will be undertaken comparing the intervention and control arms in a cost effectiveness analysis.) This will depend on the results of the study.

Previous secondary outcome measures:
1. Effective contraception use, determined by telephone contact (or survey) at 12 months
2. LARC use in both groups at 12 months
3. Proportion of participants with unintended pregnancy, self-reported using validated tool the London measure of Unintended Pregnancy, at 12 months
4. Process evaluation of the intervention; implementation, fidelity and reach (to understand why /why not the intervention works and to inform future roll out/implementation), measured from quantitative and qualitative interviews of women, and qualitative interviews of pharmacists and focus group discussions with staff from sexual ad reproductive health service at varying time points throughout the study
5. Cost effectiveness: incremental cost-effectiveness ratio at 12 months: every £100 spent on the intervention resulted in X fewer abortions for a savings of £Y (costs will include the pharmacist training to provide POP, direct and indirect costs of health service use, and the provision and dispensing of POP, abortion costs)

Completion date
26/06/2020

Eligibility

Key inclusion criteria
Current inclusion criteria as of 31/01/2019:
1. Intake of oral emergency contraception (1.5 mg or 3 mg Levonorgestrel)
2. Capacity to give informed consent to participate in the trial which includes adherence to trial requirements
3. Willing to give contact details and be contacted at 4 months by phone or text or e-mail or post
4. Willing to give identifying data sufficient to allow data linkage with NHS registries
5. Female aged 16 years or over

Previous inclusion criteria:
1. Intake of oral emergency contraception (1.5 mg Levonorgestrel)
2. Willing to participate in the trial
3. Willing to give contact details and be contacted at 4 and 12 months by phone or text or e-mail or post
4. Willing to give identifying data sufficient to allow data linkage with NHS registries
5. Female 16 years or older

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
636

Key exclusion criteria
Current exclusion criteria as of 31/01/2019:
1 Contraindications to the POP (there are very few)
2 On medication that interacts adversely with POP
3. Already using a hormonal method of contraception
4. Require interpreting services
5. If pharmacist has concerns about non-consensual sex

Previous exclusion criteria:
1. Not willing to provide contact details or personal data sufficient to allow identification /linkage with NHS registries
2. Contraindications to the POP (there are very few)
3. On medication that interacts adversely with POP
4. Age under 16
5. Already using a hormonal method of contraception
6. Require interpreting services

Date of first enrolment
16/12/2017

Date of final enrolment
26/06/2019

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Community pharmacies in NHS Lothian & Chalmers Sexual Health Centre
Chalmers Centre

2a Chlamers street
Edinburgh
United Kingdom
EH3 9ES

Study participating centre
Margaret Pyke Centre & participating community pharmacies
Mortimer Market
London
United Kingdom
wc1E6JP

Study participating centre
Kings College London Sexual Health Service & participating community pharmacies
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Community pharmacies in NHS Tayside & Tayside Sexual Health Service
Ninewells Hospital
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
University of Edinburgh

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/11/2020	16/11/2020	Yes	No
Results article		01/05/2021	06/05/2021	Yes	No
Results article	process evaluation	11/02/2022	16/05/2023	Yes	No
Protocol article	protocol	30/10/2019	22/10/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes