

The effectiveness of bridging from emergency to regular contraception

Submission date 17/03/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 20/03/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/05/2023	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English Summary

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

Study website

<https://w3.abdn.ac.uk/hsru/BRIDGE-IT/Public/Public/index.cshtml>

Contact information

Type(s)

Public

Contact name

Prof Sharon Cameron

ORCID ID

<http://orcid.org/0000-0002-1168-2276>

Contact details

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Edinburgh

United Kingdom

EH3 9ES

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 hypothesis

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

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Condition

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 measure

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 contraception (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

Secondary outcome measures

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 and 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)

Overall study start date

01/04/2017

Overall study end date

26/06/2020

Eligibility

Participant 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

Age group

Adult

Sex

Female

Target number of participants

626-737 participants total; 31 clusters, average cluster size of 12-13 in each phase

Total final enrolment

636

Participant 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

Recruitment start date

16/12/2017

Recruitment end date

26/06/2019

Locations

Countries of recruitment

England

Scotland

United Kingdom

Study participating centre

Community pharmacies in NHS Lothian & Chalmers Sexual Health Centre

Chalmers Centre
2a Chalmers 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

Sponsor details

Old College
South Bridge
Edinburgh
Scotland
United Kingdom
EH8

Sponsor type

University/education

Website

www.accord.scot

ROR

<https://ror.org/01nrxf90>

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

1. The clinical study report for NIHR/HTA will be used for publication and presentation at scientific meetings. Investigators will publish the results of the study in peer-reviewed journals
2. Summaries of results will also be made available to all participants at the end of the study

Added 20/04/2020:

The plan is to publish the primary outcome analysis by July 2020. The secondary outcome (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.) This will be collected in July 2020 and published at a later date.

Intention to publish date

31/07/2020

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?
Protocol article	protocol	30/10/2019	22/10/2020	Yes	No
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
HRA research summary			28/06/2023	No	No