

Project Title – Efficacy of medical abortion through telemedicine versus standard provision – a randomised controlled non-inferiority trial

Short title: wow 2017

Swedish title: En randomiserad studie angående medicinsk abort med rådgivning via internet jämfört med rådgivning handlagd av gynekolog och/eller barnmorska

Clinical Trial registration ID. NCT03461653

Principal Investigator. Kristina Gemzell Danielsson

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Background

It is well documented that without reasonable access to safe abortion services, women risk their health and their lives to obtain clandestine abortions from unqualified persons in unhygienic conditions. According to the World Health Organization, 19 million women experience an unsafe abortion every year and 23.000 women die from complications of unsafe abortion each year. Globally, approximately 13% of all maternal deaths are due to complications of unsafe abortion. (Sedgh 2016). In low income areas in the world as a whole, an estimated seven million women every year are admitted to hospitals for treatment of complications from unsafe induced abortions (Singh, 2006). The indirect costs of unsafe abortion include the loss of productivity from abortion-related morbidity and mortality; the effect on children's health and education if their mother dies (an estimated 220.000 children worldwide lose their mothers every year from abortion-related deaths); and secondary infertility, stigma, and other socio-psychological consequences (Grimes DA, 2006).

Medical abortion

In collaboration with WHO, medical abortion has been developed into a safe and effective method for induced abortion. Medical abortion with a combination of mifepristone and a prostaglandin analogue was first developed by our research group at the WHO-collaborating centre at the department of Obstetrics and Gynaecology, Karolinska Institutet and Karolinska University Hospital. It was introduced for clinical use in France in 1988, up to 49 days of gestation, in the UK in 1991 and in Sweden in 1992 up to 63 days of gestation. The sequential regimen of mifepristone (RU 486) followed one to two days later by the prostaglandin analogue misoprostol is used routinely for the termination of pregnancy in an increasing number of countries (von Hertzen et al., 2000, WHO, 1993, 2000, 2001). Medical abortion has the potential to reduce maternal mortality and morbidity if a simplified and demedicalized regimen is implemented. A medical abortion with mifepristone and misoprostol is a safe and effective method of abortion. When provided under supervised medical care, medical abortion has a success rate of approximately 95% to 98%. Very few serious complications result from medical abortions (WHO, 2006, 2012), RCOG, 2004). Even though mifepristone and misoprostol have been on the list of essential medicines of the WHO since 2005, there are still many countries where these medicines are not available (Gynuity Health Projects. 2007). Misoprostol is an orally active synthetic PGE1 analogue, which has become an important drug in obstetric and gynaecology because of its uterotonic and cervical priming action. It is safe, cheap, widely available and stable at room temperature. The effect is dependent on the dose as well as on the route of administration. Complications are rare during the initial 4-h period after misoprostol administration and do not warrant women to stay under medical supervision. Detailed counseling and information and the

possibility of receiving advice over telephone are likely to increase acceptability. Following our studies Swedish women now have the option to self administer misoprostol at home, which has had a major impact in Sweden as well as internationally (Fiala et al 2004, Kopp-Kallner et al., 2005). Following our study the recommendations from the Swedish Board of Health and Welfare changed and Sweden became the first European country to allow home-use of misoprostol in medical abortion. For women with an unwanted pregnancy who have decided on an abortion it is of major importance to avoid unnecessary waiting times. The possibility of home-use of misoprostol can contribute to this.

The updated guidance on Safe abortion technology by the World Health Organization (WHO 2012) emphasizes the simplifying or streamlining of abortion care to increase its access. It notes a high value on research to demedicalize abortion care, affirms that home use of misoprostol is a safe option for women, and it suggests the evaluation of internet provision and telemedicine, as further alternative service delivery channels of safe abortion, as a subject for future research.

Women-on-web

Coincidentally the public start of Internet (1991) happened at almost the same time as the introduction of medical abortion (1988). In the past 20 years Internet became a major source of information for people all over the world. As a consequence it is not surprising that women around the world started using the Internet to access information about abortion services. This reflected in the many discussion forums and online sales of misoprostol and/or mifepristone. In 2004, Women on Waves (a Dutch non-profit organization) was the first to publish instructions for women about “how to safely do an abortion yourself”. A new project “Women on Web” was thereafter initiated to support women in countries where there are no safe abortion services. On the Women on Web website (www.wow.org), women can do an interactive web-based medical consultation. The interactive web-based questionnaire consists of 25 to 30 questions that serve to provide the women with information about the medical abortion and possible alternatives and identify contra-indications and risk factors for potential complications. A doctor reviews the answers to the online consultation. If there are no contraindications, a woman with an unwanted pregnancy up to 9 weeks gestation can receive a medical abortion with medication that is delivered to her home address. The medical abortion treatment consists of 200 mg mifepristone followed by 800 mcg misoprostol sublingually 24 hours later and 400 mcg misoprostol sublingually 4 hours thereafter. The package sent to the woman also includes a pregnancy test to be used 2 weeks after the abortion, to confirm that there is no ongoing pregnancy. Women are closely guided in the process through an email helpdesk in different languages.

Our studies have shown that telemedicine and provision of medical abortion through wow is safe, acceptable and with outcomes similar to medical abortion provided traditionally following face-to-face counselling (Gomperts et al., 2008, 2011, 2014, Grossman et al., 2011). Furthermore, recently home self-assessment of the abortion outcome through a low sensitivity U-hCG test and a checklist was shown to be highly accepted to women (Sunde Oppeggaard et al., 2015, Iyengar et al., 2015). In our study on home use of misoprostol a vast majority of women (99%) stated that they would also have preferred to administer mifepristone at home. However, according to the Swedish law medical abortion has to be performed in an approved health facility. The abortion is legally defined as being performed when mifepristone is swallowed. Thus, home use of misoprostol is allowed according to the law although the expulsion of the products of conception usually occurs following the administration of misoprostol.

To evaluate whether counselling through telemedicine is non-inferior to face-to face counselling a RCT will be conducted including women who chose medical abortion up to 63 days of gestation with home administration of misoprostol and self assessment of the outcome. The results of this study could be of major importance to increase access to safe abortion services. Telemedicine counselling has never been evaluated in a RCT.

Material and Methods

Hypothesis

Counselling through telemedicine will be as effective and safe as routine face-to-face counselling.

Objectives

The overall aim of this project is to increase access to simplified medical abortion.

- To compare face-to face counseling with counseling through telemedicine in medical abortion with regard to efficacy (defined as complete abortion without on-going pregnancy or surgical intervention for incomplete abortion) evaluated 30 days after the abortion treatment based on patient follow up reports of low sensitivity uhCG, and patient records
- evaluation of safety, acceptability, surgical interventions, contraceptive uptake and unscheduled contacts.

Design

Randomised controlled non-inferiority trial.

The study design is aligned with the CONSORT (Consolidated Standards of Reporting Trials), SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) and Medical Abortion Reporting of Efficacy (MARE) and *Standardizing Abortion Research Outcomes (STAR)* STAR recommendations.

1. Setting/Centres

The Department of Obstetrics and Gynaecology, Karolinska University Hospital/ Karolinska Institutet, Stockholm, Sweden. Following amendment new sites were added: SÖS, DS, Ultragyn.

2. Participants

Women requesting medical termination of pregnancy with home administration of misoprostol and home self-assessment of outcome of treatment, with pregnancies up to 63 days gestation (based on ultrasound dating).

3. Interventions

Women with an unwanted pregnancy, with no contraindication to medical abortion and self administration of misoprostol at home, of up to 63 days gestation, will be randomised into two groups at the time of the telephone booking:

Group 1: intervention

Telemedicine counselling. Ultrasound and mifepristone at outpatient clinic, to be continued with home administration of misoprostol at 24-48 hours later and self assessment of outcome 2-3 weeks after mifepristone.

Group 2: Control

Routine appointment with the abortion clinic with face-to-face counselling, ultrasound dating and mifepristone at outpatient clinic, to be continued with home administration of misoprostol at 24-48 hours later and self assessment of outcome 2-3 weeks after mifepristone.

Both groups: Self assessment of outcome will be done by the hCG CheckTop test (Exelgyn/Veda Lab (Alençon, France) (Sunde Oppegaard et al., 2015 as used in clinical routine. A Follow-up online questionnaire to evaluate success of procedure and satisfaction with treatment, contraception uptake etc will be done approximately 2-3 weeks after mifepristone to evaluate success of procedure. An email or telephone reminder will be sent if the online contact is unsuccessful. The patient (electronic) records will be reviewed after 30 days in order to control for possible extra visits related to abortion-related complications.

4. Outcome measures

Primary outcome

Efficacy of medical abortion defined as complete abortion without ongoing intrauterine pregnancy or surgical intervention for incomplete abortion within 30 days of the abortion treatment. The outcome will be determined based on the home low sensitivity uhCG and patient records (surgical intervention).

Secondary outcomes will include safety (AE/SAE), any additional medical treatment of incomplete abortion, bleeding days and estimated amount, infection, surgical treatment for other indications than ongoing pregnancy or incomplete abortion, unscheduled contacts and visits, acceptability with the abortion counselling and treatment (in-clinic or self managed, self reported /estimated gestational length and contraceptive choice.

Incomplete abortion will be defined as products of conception remaining in the uterus with continued bleeding, bulky uterus, and open cervix at examination, possibly necessitating surgical evacuation at the discretion of the provider or at the woman's request derived from patient records.

Adverse events (AEs) will be recorded. The completeness of the abortion and any AEs will be identified by the on line follow up and by clinical examination.

Data management will be organized locally by data entry personnel and at the WHO centre, Karolinska. Data will be entered by use of a clinical trial software, checked for accuracy, and corrected after consultation of clinical records and research assistants, and reviewed monthly by the Study Coordinator at the WHO centre with further checking of clinic records as necessary.

Variables and measures

Abortions will be recorded as complete, incomplete, or failed (continuing pregnancy). A case record form (CRF) will be filled out for both groups (Group 1: telephone booking, online consultation, medication pick up, follow up (all done by the patient) and for Group 2: telephone booking, in clinic consultation (by the investigator), follow up. Data will be entered into an online password protected database (by the research midwife and investigator at each site), eCRF. The database will contain

demographic variables, gynecological history, ultrasound finding, contraceptive use, abortion treatment, any additional medical treatment or surgical intervention, unscheduled visits or contacts, bleeding and spotting (total number of days, amount in relation to menstruation), pain (less than, similar, or more than normal menstruation, pain medication enough, too much, too little), pain treatment, and acceptability (determined by responses to pretested questions).

- **Acceptability will be determined by responses to the following questions (evaluated at FU):**

1. If you ever were to have another termination of pregnancy, would you opt for the same method of counselling?
Yes/No/Doesn't matter
2. If you ever have another termination of pregnancy, would you prefer the counselling at the healthcare facility or to be responsible for your own counselling via telemedicine? 1 or 2
3. If you've previously had an abortion, how would you compare your experience this time with your previous treatment?
Much worse, Worse, Similar, Better, Much better

- Acceptability of counselling procedure

Women will be asked to rate acceptability of counselling from 1 to 4

- 1, completely acceptable;
- 2, fairly acceptable;
- 3, fairly unacceptable;
- 4, completely unacceptable.

5. Eligibility criteria

Inclusion criteria: Women 18 years old and above, requesting termination of pregnancy by means of mifepristone followed by home administration of misoprostol at ≤ 63 days of gestation, with no contraindication to medical abortion and self administration of misoprostol at home, and who have given their informed consent will be eligible for study recruitment.

Exclusion criteria: Women who do not wish to participate, women who do not want home administration of misoprostol, women who are unable to communicate in Swedish, or English, and women with symptoms and signs of ectopic pregnancy. Minors (i.e. women < 18 years of age) will not be enrolled in the study. Women seeking termination of pregnancy with no visible intrauterine pregnancy.

6. Trial process and data collection

The study protocol is designed according to the recommendations in the CONSORT statement for non-inferiority trials. The study is performed at the gynaecological outpatient department (SESAM) at the Karolinska university hospital, (and additional sites according to the amendment)

The study flow is planned as follows:

Enrolment

All women with a pregnancy up to 63 days gestation requesting termination of pregnancy by medical methods and opting for home administration of misoprostol will be invited to be included in the study at the initial telephone consultation. The women

will receive detailed information regarding the study, and give oral consent to participation.

Consent will also be obtained online and at the visit to the clinic prior to ultrasound examination and intake of mifepristone.

Allocation and treatment

Eligible women with a pregnancy up to 63 days gestation who elect to participate in the study will be randomized into either:

Group 1 telemedicine counselling. or

Group 2 standard face-to-face counselling

Study participants will be administered mifepristone and provided with misoprostol and pain medication at the time of the ultrasound scan (Group 1) or at routine counselling (Group 2).

Randomization will take place after women have given their oral informed consent at the telephone consultation. Randomization will be by opening of opaque sealed envelopes by a nurse midwife. The envelopes will be prepared by a study coordinator at the WHO center of Karolinska University Hospital who will have no further contact with women. Designated nurse/midwives and doctors will be responsible for recruiting study participants at the telephone booking and research midwives/doctors for ultrasound scans in the outpatient clinic (group1) while standard care (Group 2) will be provided according to routine.

Website

Women randomised to Group 1 (telemedicine counselling) will receive the address to a designated website. The content of counselling will include eligibility criteria, information regarding the treatment course, expected effects, side effects and signs and symptoms of complications. All women will also receive contact information to a help desk and information on when and where to contact in case of need.

Women randomised to study Group 1 will receive an appointment for an ultrasound scan, mifepristone treatment, chlamydia test and pick up of study medication. A nurse midwife/doctor will be responsible for the ultrasound scan to confirm intrauterine pregnancy and gestational length. Following the ultrasound scan mifepristone will be swallowed in the clinic according to the Swedish law. No further abortion counselling will be provided at this visit. However contraceptive counselling and prescription is provided as needed.

Follow-up

A follow-up telephone call or web-based questionnaire to assess outcomes of treatment will be done by a nurse midwife or doctor approximately three weeks following the treatment (both groups). Women in the clinical routine group could choose to come back to the clinic for follow up. Appointments for postabortion contraception will be done as required.

Randomization procedure

Randomization: We will use a computer-generated randomization scheme with a varying block size. Randomization will be performed :1 by a midwife in the abortion clinic at the time of the first telephone consultation after the patient has been judged eligible for participation and has given her oral informed consent. Allocation to study group will be done after completion of a checklist of inclusion and exclusion criteria by opening consecutively numbered opaque, sealed, envelopes containing the randomisation group for each participant. Women will be identified through a patient log.

Women will be randomly assigned to either Group I) telemedicine counselling or Group II) standard face-to-face counselling.

Women in group I will be given the address to a designated website and an appointment for ultrasound scan and pick up of medication while women in group II will be given an appointment to the abortion clinic. Medical abortion will be performed according to the Swedish national guidelines. Women will receive mifepristone (LinePharma, Paris, France) 200 mg orally at the clinic (counts as Day 1). Twenty-four to 48 hours later women self-administer 800 mcg misoprostol vaginally or sublingually (4 tabl Cytotec® 200 mcg, Pfizer, New York, USA). If bleeding has not started or is scant women will be advised to administer a second dose of 400mcg misoprostol sublingually 3 hours later. Follow-up will be done 2 weeks after treatment and outcome of abortion assessed primarily by low sensitivity urinary hCG test. The study will not be masked.

Discontinuation

After recruitment, women may withdraw from the trial at any time if they do not wish to participate. This will not affect future treatment, which will then be according to clinical standard.

Registration and reporting of suspected adverse events

Any unexpected and serious side effects and suspected adverse reactions will be immediately reported to the project leader as well as the trial data and safety monitoring board.

7. Trial start date

April 2018 with initial expected completion by Q4 2019.

AMENDMENT: Due to reorganisation of abortion care in the Stockholm region with closure of SESAM clinic at Karolinska and initial gradual but then total change to central telephone booking and the outbreak of covid-19 the project has been phased with constant delays. The time has been used to adjust logistics and for piloting the study tools, and development of the study website and database.

First patient recruited in actual trial after logistic adjustments April 29, 2020. Estimated completion Q4 2022

New trial sites added for standard care patients; Södersjukhuset, Danderyds hospital and Ultragyn.

8. Statistical analysis plan; power calculations - sample size

Sample size

The hypothesis to test is a non-inferiority hypothesis. The aim is to prove that telemedicine counseling is not inferior compared to standard abortion treatment. The expected efficacy rate (primary outcome) is 97.5% in both groups. The non-inferiority margin is set at 3%. The primary hypothesis will be tested by constructing a 95% confidence interval (CI) for the difference between the two treatments (intervention-control). If the upper limit of the CI is less than 3% the intervention will be declared as non-inferior to standard abortion care. In total 635 patients per group (1370 in total) is needed to obtain a power of 90%. To compensate for a 10% loss to FU an additional 138 women will be added to include 754 patients per group (total 1508 women).

Numbers and proportions of women having failed abortion and surgical intervention for incomplete abortion will be calculated by intervention. Both interventions will be compared using both absolute and relative measures with 95% confidence intervals. An intention-to-treat analysis as well as a per-protocol analysis will be performed. To evaluate the differences between the groups regarding independent nominal data such as side-effects and compliance, the chi squared test will be used. Continuous variables with a normal distribution, will be analysed using the Student's t-test whereas variable which are not

normally distributed, such as age, GA (self-estimate vs LMP vs US) will be presented as medians (range) and compared using Mann-Whitney U-test. Discrete numerical variables such as parity and bleeding days will be presented as means (range) and assessed for normality and comparison using the t-test or the Mann-Whitney U-test. Numeric variables (time lost from work and number of unplanned visits/consultations) will be analysed using analysis t-test. Results will be considered statistically

significant if P-value < 0.05. An independent data and safety monitoring committee will evaluate AE/SAE and make decisions if the trial should be stopped or continue as planned. Reason for stopping the trial could be a high failure rate or low acceptability rate in the intervention group. The plan for analysis and the study protocol has been developed in collaboration with prof. Johan Bring, Statisticon AB.

9. Trial data and safety monitoring board

Marc Bygdeman, MD, PhD, professor emeritus, Elin Larsson, PhD. Amanda Cleeve, RNM, PhD

10. Ethics committees and other regulatory boards

Approved by the EPN/EPM .Also submitted to the personal data officer at the University Hospital.

Significance

Worldwide it is estimated that around 56 million pregnancies are terminated each year. In countries where women lack access to safe abortion care, unsafe abortion is a significant cause of maternal mortality and morbidity. As many as 19 million women experience an unsafe abortion (18.5 million of these occur in developing countries) and approximately 13% of all maternal deaths are due to complications of unsafe abortion.

Unintended and unwanted pregnancies are a global reproductive health problem. It undermines women's schooling, health, social status and future opportunities for work. This contributes to their unequal status in society and is directly linked to poverty.

Giving women access to safe and effective contraceptive methods and safe abortion care, improves family well being and reduces abortion rates as well as maternal mortality.

Access to essential medicines is a human right. The World Health Organization's definition of health is: "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (from the preamble of the constitution of the World Health Organization, which was adopted in 1946 by all members of the World Health Organization).

Article 12 of the *International Covenant on Economic, Social and Cultural Rights* states that the right to health includes a right to enjoy available, accessible and acceptable health care consisting of a variety of goods and services necessary for the realization of the highest attainable standard of health. Goods and services related to pregnancy and its termination, including essential medicines, are necessary to the realization of the highest attainable standard of reproductive health.

Women worldwide use the internet to find information about abortion services. However, very little is known about the way women obtain information about medical abortion and their experiences doing medical abortions by themselves especially in countries where abortion is legally restricted. This study is conducted to increase access to medical abortion via telemedicine which if implemented could be a tool to reduce maternal mortality and morbidity.

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