



## C-Gyn 21

# The use of mifepristone for medical termination of pregnancy

Medical rather than surgical termination of pregnancy is the method preferred by many women when it is available and suitable for them. Mifepristone, (formerly RU486 a synthetic anti progesterone) in combination with misoprostol (prostaglandin analogue) is the best available regimen for medical termination of pregnancy. Alternative regimens are reported but are generally less effective and take longer to work.

For at least 95% of women up to 9 weeks gestation, mifepristone with misoprostol results in complete expulsion of the products of conception within a few hours, but up to 5% of women will need surgical evacuation of the uterus. Complication rates are comparable to surgical termination of pregnancy. There is also good evidence for effective regimens for medical termination of pregnancy beyond 9 weeks and in the second trimester of pregnancy.

### Access to mifepristone

Mifepristone is available in North America, the United Kingdom, much of Western Europe, Russia, China, Israel and many other countries.

In New Zealand, Mifepristone was approved by the New Zealand Medicine and Medical Device Safety Authority (MEDSAFE) on 30 August 2001 for four indications:

1. Early medical termination of pregnancy
2. Priming the cervix before a surgical termination
3. Second trimester medical termination of pregnancy
4. Induction of labour for fetal death in utero.

In Australia, mifepristone has not been approved for general use by the Therapeutic Goods Administration (TGA). Unless and until this occurs, practitioners may apply for authorized prescriber status (section 19(5) of the Therapeutic Goods Act 1989) or on a case by case basis through the Special Access Scheme (SAS), category B. See Appendix 1.

The drug is not available through pharmacies but on a restricted basis to institutions licensed to carry out termination of pregnancy. It is not available for use as a post-coital contraceptive.

### Guidelines for Mifepristone use in Medical Termination Of Pregnancy

#### **Staff and location**

- The prescribing practitioner must supervise and take responsibility for the entire process of termination of pregnancy from administration of mifepristone through to confirmation of termination of pregnancy and completion of follow-up.
- Specified suitably trained staff must be responsible for all stages of clinical care.

- This may be done in conjunction with clearly identified protocols and clinical delegations for instance within a hospital emergency department or other appropriate clinical team or unit, which include provision for surgical intervention and 24 hour emergency care as needed.
- Prescribing practitioners should have appropriate training plus adequate experience in caring for women undergoing termination of pregnancy and/or experiencing spontaneous miscarriage.
- There must be adequate staffing and facilities for uterine curettage to be performed promptly and expertly when required.
- Practitioners should have appropriate training in surgical evacuation of the uterus including the use of suction catheters, and be capable of managing complications arising from performance of these procedures. Other practitioners may have suitable experience and qualifications to prescribe mifepristone and this should be determined by the appropriate local credentialing committee.
- Medical termination should not be performed in an isolated or an inaccessible setting: there must be ready access to suitable emergency care at all times from administration of mifepristone until termination of pregnancy is complete. This includes 24/7 access to specific telephone advice and access to an emergency service staffed and equipped to assess and treat women with miscarriage. Appropriate staff should be informed and accepting of the possible presentation of women undergoing termination of pregnancy.
- In Australia the administration of the drug must be carried out by the nominated practitioner to the consented patient as specified on the SAS Category B Form.

### ***General considerations prior to pregnancy termination***

- All women should be given accurate information and offered appropriate counselling
- Clinical assessment should be undertaken including medical history and examination
- Accurate gestational assessment is essential to selecting optimal treatment options and regimens. Ultrasound examination will usually be required prior to termination of pregnancy.
- Consideration should be given to screening for STIs and/or antibiotic prophylaxis.
- Blood group and Rhesus status should be assessed if not known and anti-D given to non-sensitised Rh negative women within 72 hours of the termination in accordance with current local guidelines.
- A plan for future contraception should be made prior to undertaking termination of pregnancy.

### ***Clinical protocols***

- Protocols should be consistent with established clinical evidence, such as those published in the RCOG Evidence-based Clinical Guidelines. Mifepristone can be used in conjunction with prostaglandin for termination of pregnancy throughout the first and second trimesters of pregnancy.
- There should be written clinical protocols including dosage, administration, timing and follow up care.

- Protocols will need to have distinct provisions for early termination of pregnancy (intra-uterine pregnancy of less than 63 days gestation), late first trimester termination of pregnancy and second trimester termination of pregnancy. Late termination of pregnancy must take place in a hospital with access to all necessary clinical and psychological support. See Appendix 2.
- There should be written information for women about treatment and follow up.
- Written consent should be obtained prior to the commencement of treatment.
- Mifepristone must be taken under direct supervision in accordance with any prescribing restrictions.
- When a woman is discharged from the treatment facility, whether before or after completion of the termination of pregnancy, she should be given clear written instructions as to how to access advice on a 24 hour basis and help in an emergency, as well as information about what to expect and follow-up arrangements. She should be accompanied by a support person who has been adequately informed about what to expect, until the termination process is complete.
- Rhesus negative women should be given anti-D within 72 hours of the termination.
- A follow up appointment should be arranged to confirm that the termination is complete and that future contraception is discussed.
- Follow-up should be undertaken to ensure the termination is complete. This should include clinical assessment with serial HCG estimations and/or ultrasound examination, if required. The method and timing of initial follow up should be arranged at the time of discharge from the treatment facility. Follow-up should also confirm ongoing access to and use of effective contraception.

### **Use of Mifepristone as an Emergency Contraceptive**

- Mifepristone is not approved for this purpose in New Zealand or Australia.
- Alternative emergency contraception (e.g. IUD, Postinor, etc) should be considered.

### **Links to RANZCOG documents**

[Termination of pregnancy: a resource for health professionals](#) (2005)

### **Other useful links**

Special Access Scheme (SAS) forms: <http://www.tga.gov.au/hp/index.htm#sas>

TGA Section 19(5) Access to unapproved therapeutic goods - Authorised prescribers: <http://www.tga.gov.au/docs/html/authpres.htm>

### **References**

1. Royal College of Obstetricians and Gynaecologists. The care of women requesting induced abortion. Evidence-based Clinical Guideline Number 7. London: RCOG; 2004. [http://www.rcog.org.uk/resources/public/pdf/induced\\_abortionfull.pdf](http://www.rcog.org.uk/resources/public/pdf/induced_abortionfull.pdf)
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4. Cheng L, Gulmezoglu AM, Oel CJ, Piaggio G, Ezcurra E, Look PF. Interventions for emergency contraception. [see comment] [update of Cochrane Database Syst Rev. 2000;(2):CD001324; PMID: 10796776]. [Review] [125 refs]. Cochrane Database of Systematic Reviews. (3):CD001324, 2004.
5. Shand C, Irvine H, Iyengar V. Guidelines for the use of mifepristone medical abortion in New Zealand: Abortion Supervisory Committee; 2004.
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<http://www.rcog.org.uk/index.asp?PageID=662>

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